

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

INDIVIDUALLY AND

**Case No.**

Plaintiff,

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

vs.

**JURY TRIAL DEMANDED**

STEMLINE THERAPEUTICS, INC., IVAN  
BERGSTEIN, and DAVID GIONCO,

Defendants.

Plaintiff [REDACTED] (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Stemline Therapeutics, Inc. (“Stemline” or the “Company”),

and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired Stemline securities: (1) pursuant and/or traceable to Stemline's secondary public offering on or about January 20, 2017 (the "Offering"); and/or (2) publicly traded on the open market between January 19, 2017 and February 1, 2017, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws under the Securities Act of 1933 (the "Securities Act") and under the Securities Exchange Act of 1934 (the "Exchange Act").

### **JURISDICTION AND VENUE**

2. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o), and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

4. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). The Company is headquartered in this Judicial District, and a significant portion of Defendants' actions, and the subsequent damages, took place in this Judicial District.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Stemline securities pursuant and/or traceable to the Company's Offering and/or during the Class Period and was economically damaged thereby.

7. Defendant Stemline is a clinical stage biopharmaceutical company that focuses on the discovery, acquisition, development, and commercialization of proprietary oncology therapeutics in the United States. The Company is incorporated in Delaware and its principal executive offices are located at 750 Lexington Avenue, Eleventh Floor, New York, New York 10022. Stemline's common stock is traded on The NASDAQ Capital Market ("NASDAQ") under the ticker symbol "STML."

8. Defendant Ivan Bergstein ("Bergstein") founded Stemline in August 2003 and has been its Chairman, Chief Executive Officer ("CEO") and President since August 2003.

9. Defendant David Gionco ("Gionco") has been the Chief Accounting Officer and Vice President of Finance of Stemline since December 16, 2013 and January 16, 2014, respectively.

10. Defendants Bergstein and Gionco are collectively referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

- (b) was directly involved in the day-to-day operations of the Company at the highest levels;
- (c) was privy to confidential proprietary information concerning the Company and its business and operations;
- (d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- (e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;
- (f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (g) approved or ratified these statements in violation of the federal securities laws.

12. Stemline is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

13. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to Stemline under *respondeat superior* and agency principles.

14. Defendants Stemline and the Individual Defendants are collectively referred to herein as "Defendants."

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

15. The Offering was made by Stemline pursuant to a shelf registration statement on

Form S-3 that was previously filed with the SEC on February 3, 2014, and declared effective by the SEC on February 12, 2014 (the “Registration Statement”). The Registration Statement was signed by Defendants Bergstein and Gionco.

16. Stemline is presently conducting an ongoing pivotal Phase 2 trial in blastic plasmacytoid dendritic cell neoplasm (“BPDCN”), using Stemline’s experimental compound, SL-401. At present, BPDCN has no approved treatment.

17. On January 18, 2017, a cancer patient in a Stemline clinical trial tied to SL-401 died from a severe side effect.

18. On January 20, 2017, Stemline commenced the Offering, offering 4.5 million shares of its common stock at \$10.00 per share, with expected gross proceeds to Stemline of \$45 million.

19. On January 20, 2017, Stemline filed a Form 424B5 with the SEC, containing Stemline’s Prospectus Supplement, dated January 20, 2017, for the Offering (the “Prospectus” and together with the Registration Statement, the “Offering Documents”).

**Materially False and Misleading  
Statements Issued During the Class Period**

20. On January 19, 2017, Stemline issued a press release entitled “Stemline Therapeutics Announces Proposed Public Offering of Common Stock,” announcing a public offering of its common stock to fund, among other things, potential commercial activities of SL-401, stating in pertinent part:

**Stemline Therapeutics Announces Proposed Public Offering of Common  
Stock**

*January 19, 2017 16:03 ET* | **Source:** Stemline Therapeutics

NEW YORK, Jan. 19, 2017 (GLOBE NEWSWIRE) -- **Stemline Therapeutics, Inc.** (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, today announced that it intends to offer and sell, subject to market conditions, shares of its common stock in an underwritten public offering. All of the shares to be sold in the offering will be offered by Stemline. In addition, Stemline intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of its common stock offered in the public offering.

Jefferies LLC is acting as book-running manager for the offering.

Stemline intends to use the net proceeds from the public offering for (i) clinical, regulatory, manufacturing and, if and when approved, potential commercial activities of SL-401; (ii) clinical development of SL-801 and SL-701; (iii) research and development activities; and (iv) other general corporate purposes.

Stemline has filed a preliminary prospectus supplement to its shelf registration statement on Form S-3 (File No. 333-193726) with the U.S. Securities and Exchange Commission for the proposed public offering of its common stock. The offering will be made only by means of a prospectus supplement and the accompanying prospectus, which will be available on the SEC's web site at [www.sec.gov](http://www.sec.gov). Copies of the preliminary prospectus supplement relating to these securities may also be obtained, when available, by contacting Jefferies LLC, Attention: Equity Syndicate Prospectus Department, 520 Madison Avenue, 2nd Floor, New York, NY, 10022, or by telephone at 877-547-6340, or by email at [prospectus\\_department@jefferies.com](mailto:prospectus_department@jefferies.com).

The offering of these securities is being made under an effective shelf registration statement on file with the U.S. Securities and Exchange Commission. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

21. On January 20, 2017, Stemline issued a press release entitled “Stemline Therapeutics Prices \$45 Million Public Offering of Common Stock,” announcing the pricing of the offering of 4.5 million shares of its common stock at \$10.00 per share, with expected gross proceeds to Stemline of \$45 million, stating in pertinent part:

**Stemline Therapeutics Prices \$45 Million Public Offering of Common Stock**

*January 20, 2017 09:00 ET* | **Source:** Stemline Therapeutics

NEW YORK, Jan. 20, 2017 (GLOBE NEWSWIRE) -- **Stemline Therapeutics, Inc.** (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, today announced the pricing of an underwritten public offering of 4.5 million shares of its common stock at a price of \$10.00 per share, with expected gross proceeds to Stemline of \$45 million. In addition, Stemline has granted the underwriters a 30-day option to purchase up to 675,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. The offering is expected to close on January 25, 2017, subject to customary closing conditions.

Jefferies LLC and Cowen and Company, LLC are acting as joint book-running managers for the offering. Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co. are acting as co-lead managers and Roth Capital Partners, Joseph Gunnar & Co., LLC and Aegis Capital Corp. are acting as co-managers for the offering. Stemline intends to use the net proceeds from the public offering for (i) clinical, regulatory, manufacturing and, if and when approved, potential commercial activities of SL-401; (ii) clinical development of SL-801 and SL-701; (iii) research and development activities; and (iv) other general corporate purposes.

The offering is being made by Stemline pursuant to a shelf registration statement on Form S-3 previously filed with the Securities Exchange Commission (the "SEC") on February 3, 2014 and declared effective by the SEC on February 12, 2014. The offering is being made only by means of a written prospectus and prospectus supplement that form a part of the registration statement. A preliminary prospectus supplement and accompanying prospectus related to the offering has been filed with the SEC and is available on the website of the SEC at [www.sec.gov](http://www.sec.gov). When available, copies of the final prospectus supplement and accompanying prospectus may be obtained from Jefferies LLC, Attn: Equity Syndicate Prospectus Department, 520 Madison Ave, 2nd Floor, New York, NY 10022, by telephone at (877) 821-7388 or by email at [Prospectus\\_Department@Jefferies.com](mailto:Prospectus_Department@Jefferies.com) or Cowen and Company, LLC, c/o Broadridge Financial Services, 1155 Long Island Avenue, Edgewood, NY, 11717, Attention: Prospectus Department, or by telephone at 631-274-2806, or by faxing 631-254-7140.

22. The Prospectus discussed the clinical trials of Stemline's clinical stage product candidate, SL-401, stating in pertinent part:

### **Overview**

We are a clinical stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing proprietary oncology therapeutics. We are currently developing three clinical stage product candidates, SL-401, SL-801, and SL-701.

## Recent Developments

On January 5, 2017, we announced an agreement with the U.S. Food and Drug Administration, or FDA, on the registration pathway for SL-401 in blastic plasmacytoid dendritic cell neoplasm, or BPDCN. To support the filing of a Biologics License Application, or BLA, for full approval in first-line BPDCN, we are currently enrolling an additional small patient cohort, into our ongoing Phase 2 trial. This cohort is expected to enroll between 8-12 first-line BPDCN patients. To date, approximately half of these new patients have been enrolled into the study.

On December 31, 2016 and September 30, 2016, we had cash, cash equivalents, short-term investments and long-term investments of approximately \$67.6 million and \$74.3 million, as compared to \$97.5 million and \$104.0 million, as of December 31, 2015 and September 30, 2015, respectively.

## SL-401

Patients are currently enrolling in SL-401 clinical trials in multiple indications, including a potentially pivotal Phase 2 trial in patients with BPDCN. SL-401 as a single agent is also being advanced through clinical trials in myeloproliferative neoplasms, or MPN, and acute myeloid leukemia, or AML. In addition, SL-401 is being evaluated in combination with certain traditional therapies in a Phase 1/2 trial in patients with relapsed or refractory, or r/r, multiple myeloma.

SL-401 is a targeted therapy directed to the interleukin-3 receptor, or IL-3R (CD123). CD123 is present on a wide range of hematologic cancers including BPDCN, certain MPNs, AML, multiple myeloma, hairy cell leukemia, myelodysplastic syndrome, or MDS, chronic myeloid leukemia, or CML, and other myeloid and lymphoid malignancies. SL-401 has demonstrated anti-tumor activity against a wide range of hematologic cancers in *in vitro* and *in vivo* preclinical models, including BPDCN, MPN, AML, multiple myeloma, CML, and other leukemic and lymphoid malignancies.

Previously, SL-401 was evaluated in an investigator-sponsored Phase 1/2 clinical trial in patients with advanced hematologic cancers; a trial which has since completed. In this trial, SL-401 was administered via daily intravenous infusion for up to five days, for only a single cycle, and demonstrated a manageable safety profile and anti-tumor activity, including complete responses, or CRs, largely in BPDCN but also in r/r AML (Frankel et al. Blood 124, 2014; ASH 2013 Poster #2682; ASH 2015 Poster #3795).

Currently, we are enrolling patients in the following corporate-sponsored SL-401 clinical trials in which SL-401 is administered in a multi-cycle regimen (via daily intravenous infusion for up to five days, repeated every 3-4 weeks):



- A Phase 2 potentially pivotal trial in patients with BPDCN;
- A Phase 2 trial in patients with advanced, high-risk MPNs;
- A Phase 2 trial in patients with AML in CR with minimal residual disease, or MRD; and
- A Phase 1/2 trial, in combination with pomalidomide and dexamethasone, in patients with r/r multiple myeloma.

SL-401 was granted BTB by the FDA in August 2016. In addition, SL-401 was granted Orphan Drug Designation for the treatment of BPDCN and AML from both the FDA and the European Medicines Agency, or EMA.

### **SL-401 in BPDCN**

Patients are currently enrolling into our ongoing, potentially pivotal Phase 2 trial of SL-401 in BPDCN. The trial is a single arm, open-label, multicenter study. The trial consists of a lead-in, dose escalation stage that included BPDCN and relapsed/refractory AML patients (Stage 1) followed by an expansion stage of BPDCN patients only (Stage 2) that utilizes the dose and regimen determined in Stage 1. Both Stage 1 and Stage 2 have completed enrollment.

To support a BLA filing for full approval in first-line BPDCN, Stemline is currently enrolling first-line BPDCN patients in an additional cohort (Stage 3) that is expected to enroll between 8-12 first-line BPDCN patients.

During 2016, our academic investigators delivered oral presentations on the SL-401 Phase 2 clinical data in BPDCN at the annual meetings of the American Society of Clinical Oncology, or ASCO, in Chicago, Illinois, the European Hematology Association, or EHA, in Copenhagen, Denmark, and the American Society of Hematology, or ASH, in San Diego, California.

As of the 2016 ASH annual meeting, 32 adult BPDCN patients received SL-401 in a multi-cycle regimen. SL-401's safety profile has continued to remain predictable and manageable over increasing treatment duration, drug exposure, and patient experience. In first-line patients who received SL-401 at the recommended dose of 12 ug/kg/day, the ORR was 100% (16/16) with a CR rate of 81% (13/16). In relapsed/refractory patients, the ORR was 69% (9/13) with a CR rate of 31% (4/13). Across all lines and all doses, ORR was 84% (27/32) with CR rate of 56% (18/32). CRs include clinical complete responses, or CRc, defined as a CR in non-skin organs with gross reduction in cutaneous lesions and residual microscopic skin disease, and CRi, defined as CR with incomplete hematologic recovery. 69% (11/16) first-line patients who received SL-401 at 12 ug/kg/day were progression-free (range: 1<sup>+</sup> to 20<sup>+</sup> months, ongoing), including 5 patients receiving ongoing SL-401 (range: 1<sup>+</sup> to 15<sup>+</sup> months, ongoing) and 6 patients who

were successfully bridged to stem cell transplant, or SCT (progression-free range from first SL-401 dose: 5<sup>+</sup> to 20<sup>+</sup> months, ongoing). 46% (6/13) relapsed/refractory patients were progression-free (range: 1<sup>+</sup> to 8<sup>+</sup> months, ongoing), including 5 patients receiving ongoing SL-401 (range: 1<sup>+</sup> to 4<sup>+</sup> months, ongoing) and 1 patient who was successfully bridged to SCT (progression-free from first SL-401 dose: 8<sup>+</sup> months, ongoing). Progression-free survival, or PFS, and overall survival, or OS, data continue to trend favorably and patients continue to be followed.

### **SL-401 in high-risk myeloproliferative neoplasms**

We are currently enrolling patients with certain advanced, high-risk myeloproliferative neoplasm, or MPNs, including chronic myelomonocytic leukemia, or CMML, myelofibrosis, systemic mastocytosis, and primary eosinophilic disorders, in a single arm, open-label, multicenter Phase 2 clinical trial. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of this clinical study are to determine 1) safety and optimal dose in this indication, and 2) signals of clinical activity. Stage 1 of this trial has been completed and enrollment in Stage 2 is ongoing.

### **SL-401 in AML in remission with high relapse risk including minimal residual disease**

We are currently enrolling AML patients in CR with minimal residual disease, or MRD, in a single arm, open-label, multicenter Phase 2 clinical trial. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of the clinical study are to determine 1) safety and optimal dose in this indication, 2) signals of clinical activity which includes SL-401's potential ability to lessen MRD burden, and 3) whether CR duration can be extended by SL-401 relative to historical data. Stage 1 of the trial has been completed and enrollment in Stage 2 is ongoing.

### **SL-401 in combination with pomalidomide and dexamethasone in relapsed/refractory multiple myeloma**

We are currently enrolling patients in a single arm, open-label, multicenter Phase 1/2 clinical trial evaluating SL-401 in combination with pomalidomide and dexamethasone in r/r multiple myeloma patients. This trial has a lead-in dose escalation stage (Stage 1) and an expansion stage (Stage 2) designed to enroll patients at the dose and regimen determined by Stage 1. The objectives of the clinical study are to determine 1) the safety and optimal dose of SL-401 when administered in combination with pomalidomide and dexamethasone and 2) signals of clinical activity. The trial is currently enrolling patients in Stage 1.

### **Additional planned Phase 1/2 trials of SL-401**

We are planning additional Phase 1/2 trials of SL-401 in a variety of other indications.

23. The Prospectus also touted SL-401's favorable clinical data as of the date of the Prospectus, January 20, 2017, stating in pertinent part

Based upon **favorable clinical data observed to date with SL-401** and SL-701 across several indications, we plan to initiate multiple clinical trials with SL-401 in a variety of hematologic cancers and with SL-701 in advanced adult and pediatric brain cancers. These include pivotal programs with SL-401 in BPDCN and late-stage AML. We also plan to initiate Phase 1/2 trials in additional hematologic indications including several rare malignancies, multiple myeloma, and earlier stages of AML. In addition, we plan to initiate a Phase 2 trial of SL-701 in adult patients with glioblastoma multiforme, or GBM, who failed one previous treatment, i.e., second line GBM; a study which could potentially provide the basis for accelerated approval. In addition, we plan to initiate a Phase 2 trial of SL-701 in pediatric patients with brainstem and non-brainstem high-grade glioma.

[Emphasis added].

24. The statements contained in ¶¶ 20 - 23 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) a cancer patient in a Stemline clinical trial tied to SL-401 died from a severe side effect on January 18, 2017; and (2) as a result of the foregoing, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

### **THE TRUTH EMERGES**

25. On February 2, 2017, before market opened, *TheStreet* published an article entitled "Side Effect Kills Cancer Patient in Stemline Therapeutics Drug Trial, the Company

Raises Money,” revealing that on January 18, 2017, one day prior to Stemline’s Offering, a cancer patient in a Stemline clinical trial tied to SL-401 died from a severe side effect, stating in relevant part:

**Side Effect Kills Cancer Patient in Stemline Therapeutics Drug Trial, the Company Raises Money**

Stemline’s SL-401 has demonstrated robust overall tumor response rates in its clinical trial but the drug is also now tied to three patient deaths from capillary leak syndrome.

Adam Feuerstein  
Feb 2, 2017 6:00 AM EST

**Investors who bought into a \$45 million Stemline Therapeutics (STML) stock offering on Jan. 19 were not told that one day prior to the financing, a cancer patient in a clinical trial died from a severe side effect, a type of low blood pressure, tied to the company’s drug SL-401.**

Stemline has disclosed two previous patient deaths related to the same SL-401 toxicity -- capillary leak syndrome.

**The third death in Stemline’s SL-401 study due to capillary leak syndrome, not yet reported by the company but confirmed by a member of the patient’s family, is potentially troubling because it occurred after Stemline had already increased safety monitoring and added new dosing rules to reduce the incidence and severity of the side effect.**

Capillary leak syndrome occurs when large volumes of plasma and other blood components leak from blood vessels into the body cavity. This leads to swelling and a sharp drop in blood pressure that can cause organ failure and death.

The inability to control serious, potentially fatal, side effects can derail otherwise highly effective experimental therapies, even cancer drugs. Last year, the U.S. Food and Drug Administration placed a clinical hold on a promising CAR-T cancer therapy from **Juno Therapeutics (JUNO)** because a handful of patients died from brain swelling. The Juno therapy remains on FDA clinical hold to this day, with most investors believing the company will be forced to abandon further development.

To date, SL-401 has demonstrated robust overall tumor response rates of 84%, including 56% complete or near-complete response in patients enrolled in its

clinical trial. But the drug is also now tied to three patient deaths. Stemline cannot afford a safety setback or FDA clinical hold similar to what happened to Juno.

The company is rushing to complete enrollment totaling approximately 50 patients in the SL-401 phase II study by the end of the current quarter. Stemline intends to use the study as the basis for a marketing application to the FDA in the second half of the year.

That's an aggressive timeline but one that could secure Stemline's first-ever cancer drug approval in 2018. If approved, SL-401 would be used to treat blastic plasmacytoid dendritic cell neoplasm (BPDCN), a ultra-rare blood cancer that attacks a specialized form of immune cells.

Stemline was asked to confirm and provide more details about the death of the BPDCN patient on Jan. 18, one day before the company sold 4.5 million shares of stock at \$10 per share. In response, Stemline Chief Operating Officer Ken Hoberman provided the following statement:

We are not in a position to comment about any specific outcomes that may or may not have occurred in any of our existing trials. As you know, in any trial of an experimental agent for patients with advanced cancer, patient deaths often occur. When deaths occur in a trial, then careful analysis must be done to understand probable causes and relation, if any, of the death to the use of the experimental product. It would be inappropriate for Stemline to comment on the death of any patient or patients in a trial, including any trial of SL-401, until such an analysis has been conducted, has concluded, and has yielded any information that should be shared publicly.

According to her sister, who spoke with *TheStreet*, the patient in question was diagnosed with BPDCN last fall and recruited into Stemline's pivotal clinical trial for SL-401. The drug is administered as a daily infusion for five days, every three weeks.

The patient received the first two doses of SL-401 on Jan. 12 and 13. Her third daily infusion was postponed because of deteriorating health due to side effects. **On Jan. 17, the patient was diagnosed with capillary leak syndrome. She died the next day, never having received three of the scheduled five doses of SL-401 in the initial treatment cycle of the clinical trial.**

"It happened really fast, out of nowhere... We had lunch together the week before she went into the hospital. She was fine," said the patient's sister. [The patient is not being identified by name for privacy reasons.]

Stemline identified capillary leak syndrome as a serious side effect of SL-401 during the initial, dose-ranging stage of the phase II study, which enrolled 15 patients. One BPDCN patient died due to capillary leak syndrome. The same cause of death was suspected for a second patient diagnosed with advanced acute myeloid leukemia, according to Stemline filings with the Securities and Exchange Commission.

During the dose-ranging stage of the phase II study, Stemline implemented additional safety precautions to reduce the risk of capillary leak syndrome before enrolling additional BPDCN patients into the expansion stage of the study.

The extra safety vigilance appeared to be working. When Stemline last presented interim results from the SL-401 phase II study in December at the American Society of Hematology annual meeting, none of the subsequently enrolled BPDCN patients had experienced severe (worse than grade 2) capillary leak syndrome.

**But that clean safety streak ended with the death of the BPDCN patient on Jan. 18, raising concerns that Stemline may not have the risk of fatal capillary leak syndrome under control.**

[Emphasis added].

26. On February 2, 2017, Stemline issued a press release entitled “Stemline Therapeutics Provides Update on Pivotal BPDCN Trial,” confirming that on January 18, 2017, a cancer patient in a Stemline clinical trial tied to SL-401 died from a severe side effect, stating in pertinent part:

**Stemline Therapeutics Provides Update on Pivotal BPDCN Trial**

*February 02, 2017 15:24 ET* | **Source:** Stemline Therapeutics

NEW YORK, Feb. 02, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, provides an update on its ongoing pivotal Phase 2 trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), using Stemline’s experimental compound, SL-401. BPDCN at present has no approved treatment.

**On January 18, the Company received a report that a patient death had occurred. The patient had developed capillary leak syndrome (CLS), a known, sometimes fatal, and well-documented side effect of SL-401.** The cause of the patient’s death has not yet been determined. The safety profile for SL-401 includes CLS, and there have been previous deaths reported in patients

with CLS in this trial, which have been disclosed in public presentations. That CLS is an expected complication of the administration of SL-401 has also been identified in filings with the Securities and Exchange Commission (SEC) and U.S. Food and Drug Administration (FDA), as well as in the study's informed consent forms and other information provided to investigators.

As with all study events, the Company has and will continue to report the data to the FDA in accordance with the study protocol and applicable regulations. Stemline plans to provide a clinical and safety update on this cohort when the cohort and data are complete. The pivotal Phase 2 trial with SL-401 in BPDCN is currently ongoing, patient enrollment is ahead of schedule, and patients continue to receive SL-401 in the trial. Our timelines for study completion and BLA submission remain on track.

[Emphasis added].

27. On this news, shares of Stemline fell \$4.15 per share or approximately 42.5% from its previous closing price on unusually high volume to close at \$5.60 per share on February 2, 2017, damaging investors.

28. At the time of the filing of this action, Stemline securities trade at approximately \$6.29 per share.

#### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

29. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired Stemline securities publicly traded during the Class Period, and/or pursuant and/or traceable to the Offering, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Stemline, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Officer or Director Defendants have or had a controlling interest.

30. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Stemline securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and

can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

31. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

32. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

33. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business Stemline;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused Stemline to issue false and misleading SEC filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and SEC filing
- whether the prices of Stemline's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.



34. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

35. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Stemline shares met the requirements for listing, and were listed and actively traded on NASDAQ, a highly efficient and automated market;
- As a public issuer, Stemline filed periodic public reports with the SEC and NASDAQ;
- Stemline regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- Stemline was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

36. Based on the foregoing, the market for Stemline securities promptly digested current information regarding Stemline from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

37. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in

their Class Period statements in violation of a duty to disclose such information as detailed above.

**COUNT I**

**For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder  
Against All Defendants**

38. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

39. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

40. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

41. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Stemline securities during the Class Period.

42. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Stemline were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of

such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of Stemline, their control over, and/or receipt and/or modification of Stemline's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Stemline, participated in the fraudulent scheme alleged herein.

43. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Stemline personnel to members of the investing public, including Plaintiff and the Class.

44. As a result of the foregoing, the market price of Stemline securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Stemline securities during the Class Period in purchasing Stemline securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

45. Had Plaintiff and the other members of the Class been aware that the market price of Stemline securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased Stemline securities at the artificially inflated prices that they did, or at all.

46. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

47. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of Stemline securities during the Class Period.

## **COUNT II**

### **Violations of Section 20(a) of the Exchange Act** **Against the Individual Defendants**

48. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

49. During the Class Period, the Individual Defendants participated in the operation and management of Stemline, and conducted and participated, directly and indirectly, in the conduct of Stemline's business affairs. Because of their senior positions, they knew the adverse non-public information about Stemline's misstatement of revenue and profit and false financial statements.

50. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Stemline's financial condition and results of operations, and to correct promptly any public statements issued by Stemline which had become materially false or misleading.

51. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Stemline disseminated in the marketplace during the Class Period concerning Stemline's results of operations. Throughout the Class Period, the Individual

Defendants exercised their power and authority to cause Stemline to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were “controlling persons” of Stemline within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Stemline securities.

52. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Stemline.

### **COUNT III**

#### **Violation of Section 11 of the Securities Act Against All Defendants**

53. Plaintiff repeats and realleges each and every allegation contained above.

54. The Offering Documents for the Offering was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

55. Stemline is the registrant for the Offering. Defendants are responsible for the contents of the Offering Documents based upon their status as directors of the Company or because they signed or authorized the signing of the Registration Statement on their behalf pursuant to Sections 11(a)(1)-(3) of the Securities Act.

56. As issuer of the shares, Stemline is strictly liable to Plaintiff and the Class for the misstatements and omissions.

57. Stemline is strictly liable for the contents of the Offering Documents. Defendants failed to make a reasonable investigation or possess reasonable grounds for the belief that the statements contained in the Offering Documents were true and without omissions of any material facts and were not misleading.

58. By reasons of the conduct herein alleged, each Defendant named in this Count violated Section 11 of the Securities Act.

59. Plaintiff acquired Stemline shares pursuant to the Offering Documents.

60. Plaintiff and the Class have sustained damages. The value of Stemline shares has declined substantially subsequent to and due to Defendants' violations.

61. At the times Plaintiff purchased Stemline shares, Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the Offering. Less than one year has elapsed from the time that Plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time that Plaintiff filed this Complaint. Less than three years elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Plaintiff filed this Complaint.

#### **COUNT IV**

##### **Violations of Section 15 of the Securities Act Against Individual Defendants**

62. Plaintiff repeats and realleges each and every allegation contained above.

63. This claim is asserted against the Individual Defendants, each of whom was a control person of Stemline during the relevant time period.

64. For the reasons set forth above in the First Claim, above, Stemline is liable to the Plaintiff and the members of the Class who purchased Stemline shares in the Offering based on the untrue statements and omissions of material fact contained in the Offering Documents and Prospectus, pursuant to Section 11 of the Securities Act, and were damaged thereby.

65. The Individual Defendants were control persons of Stemline by virtue of, among other things, their positions as senior officers of the Company, and they were in positions to

control and did control, the false and misleading statements and omissions contained in the Offering Documents.

66. None of the Individual Defendants made reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Offering Documents were accurate and complete in all material respects. Had they exercised reasonable care, they could have known of the material misstatements and omissions alleged herein.

67. This claim was brought within one year after the discovery of the untrue statements and omissions in the Offering Documents and within three years after Stemline shares were sold to the Class in connection with the Offering.

68. By reason of the misconduct alleged herein, for which Stemline is primarily liable, as set forth above, the Individual Defendants are jointly and severally liable with and to the same extent as Stemline pursuant to Section 15 of the Securities Act.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, plaintiff, on behalf of himself and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.