United States Court of Appeals
For the First Circuit

No. 21-1657

MYO THANT, Individually and on Behalf of All Others Similarly Situated,

Plaintiff, Appellant,

HEATHER MEHDI,

Plaintiff,

v.

KARYOPHARM THERAPEUTICS INC.; MICHAEL G. KAUFFMAN; SHARON SHACHAM; JUSTIN A. RENZ; MICHAEL F. FALVEY; GAREN G. BOHLIN, MIKAEL DOLSTEN; SCOTT GARLAND; BARRY E. GREENE; MANSOOR RAZA MIRZA; DEEPA R. PAKIANATHAN; KENNETH E. WEG,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Barron, Chief Judge,
Gelpí, Circuit Judge,
and Katzmann,* Judge.

Adam M. Apton, with whom Nicholas I. Porritt, Shannon L.

* Of the United States Court of International Trade, sitting by designation.

Hopkins and Levi & Korsinksy, LLP, were on brief, for appellant.
Michael G. Bongiorno, with whom Peter A. Spaeth, Allyson Slater, Jocelyn M. Keider, Joseph M. Levy, and Wilmer Cutler Pickering Hale and Dorr LLP were on brief, for appellees.

August 5, 2022

KATZMANN, Judge. Following a decline in the stock price of Karyopharm Therapeutics, Inc., investors (among them, plaintiff-appellant Dr. Myo Thant) filed suit against the company and its corporate officers (together "Karyopharm" or "defendants") alleging securities fraud in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 18 C.F.R. § 240.10b-5. In relevant part, the complaint alleged that Karyopharm materially misled investors as to the safety and efficacy of Karyopharm's cancer-fighting drug candidate selinexor. The district court dismissed the complaint, finding that plaintiffs failed to adequately plead scienter with respect to defendants' statements about the STORM[1] trial: a single-arm study of the drug selinexor as a treatment for penta-refractory multiple myeloma. Plaintiff-appellant Thant timely appealed.

We now affirm the district court's dismissal on different grounds, concluding that Thant has not plausibly alleged an actionable statement or omission with respect to the STORM trial disclosures.

I.

The complaint alleges the following. See Clorox Co. P.R. v. Proctor & Gamble Com. Co., 228 F.3d 24, 30 (1st Cir. 2000)

[1] "Selinexor Treatment of Refractory Myeloma."

(noting that in reviewing a motion to dismiss, we accept all well-pleaded facts in the complaint as true). Karyopharm is a Massachusetts-based biopharmaceutical company that develops and commercializes treatments for cancer, among other serious diseases. One of the drugs in Karyopharm's portfolio is selinexor, a cancer-fighting drug now on the market as a fifth-line treatment (in combination with the steroid dexamethasone) for patients suffering from relapsed or refractory multiple myeloma and acute myeloid leukemia. In laymen's terms, a relapsed or refractory disease is one which has not been eradicated despite treatment, or which has returned at least once following initially successful treatment.

Roughly a decade ago, Karyopharm began conducting clinical tests on selinexor to evaluate its safety and efficacy as a treatment for advanced cancers. The first such test was the Phase 1 KCP-330-001 trial, which treated patients with multiple myeloma who had received at least three prior lines of treatment or therapy without success. The results of this trial were mixed. Patients in the monotherapy arm (treated with selinexor alone) largely saw no improvement in their disease, with only one of fifty-six patients experiencing a "partial response" -- in other words, a decrease in the extent of the patient's cancer. Patients in the combination therapy arm (treated with a combination of selinexor and dexamethasone) had somewhat more positive outcomes, with 8.6%

of patients experiencing a partial response or full remission. Overall, most patients participating in the trial experienced stable or progressive disease. Importantly for the purposes of this case, data from the KCP-330-001 trial evinced a substantial level of toxicity attributable to selinexor.

Phase 2 testing of selinexor began in June 2014 with the SOPRA[2] trial, which treated patients with relapsed or refractory acute myeloid leukemia ("AML") aged sixty or above who were ineligible for standard chemotherapy or transplantation. The SOPRA trial was ultimately terminated before its completion on March 2, 2017 after "Karyopharm 'claimed at that time that it had determined, in concert with SOPRA's Independent Data Safety Monitoring Board, . . . that the study would not reach statistical significance for showing . . . the study's primary endpoint,'" namely, the superiority of selinexor alone as a treatment for AML. Indeed, the data obtained prior to SOPRA's termination showed a comparatively lower overall survival rate for patients treated with selinexor alone versus those receiving standard care (some combination of supportive care, azacitidine, decitabine, and low dose cytosine arabinoside).[3] As with the KCP-330-001 trial,

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[2] "Selinexor in Older Patients with Relapsed/Refractory AML."

[3] Azacitidine (also known by the brand name Vidaza) and decitabine (also known by the brand name Dacogen) are cytotoxic drugs which function by altering gene expression to reduce the growth of cancerous cells. PubChem, Decitabine,

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