Opna Bio Announces Orphan Drug Designation Granted to OPN-2853 (Zavabresib) for the Treatment of Myelofibrosis

SOUTH SAN FRANCISCO, CA – January 21, 2026 – Opna Bio, a clinical-stage biopharmaceutical company focused on the discovery and development of novel oncology therapeutics, today announced that OPN-2853, a bromodomain and extra-terminal motif (BET) small molecule inhibitor, has been granted Orphan Drug Designation (ODD) for the treatment of myelofibrosis (MF) by the U.S. Food and Drug Administration (FDA). Additionally, the generic name of zavabresib for OPN-2853 has been approved by the International Nonproprietary Names (INN) for Pharmaceutical Substances.

Myelofibrosis is a rare and serious type of blood cancer characterized by bone marrow scarring, which leads to ineffective blood cell production and symptoms such as severe fatigue, enlarged spleen, and anemia. Myelofibrosis affects approximately 25,000 people in the U.S.

"Receiving Orphan Drug Designation for zavabresib in myelofibrosis is a significant regulatory milestone for Opna Bio and highlights the urgent need for new and effective treatment options for patients with this disease," said **Reinaldo Diaz, chief executive officer of Opna Bio**. "Our investigator-sponsored clinical trial with zavabresib and ruxolitinib has shown impressive results to date, including durable spleen reduction in patients with advanced myelofibrosis. We believe that selective BET inhibition alongside JAK inhibition offers a promising new therapeutic approach for patients with myelofibrosis. We are further encouraged by recent positive meetings with the FDA to continue to test zavabresib in additional clinical studies."

The FDA grants Orphan Drug Designation to investigational therapies intended for the treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States. The designation provides several benefits, including tax credits for clinical trial costs, a waiver of certain FDA fees, and eligibility for seven years of market exclusivity upon approval.

In the ongoing Phase 1 PROMise study led by Professor Adam Mead at the University of Oxford through a collaboration with Cancer Research UK (CRUK), zavabresib is being evaluated as an add-on to ruxolitinib in patients with myelofibrosis who are no longer responding to ruxolitinib. Data presented at the American Society of Hematology conference in December 2025 showed a 50% or greater reduction of spleen length in 16 of 26 evaluable patients on the combination treatment when compared to baseline.

About Opna Bio

Opna Bio is a clinical-stage biopharmaceutical company focused on the discovery and

development of novel oncology therapeutics. The company's broad portfolio targets multiple drivers of cancer, including OPN-6602, a dual EP300/CBP inhibitor, currently in a Phase 1 clinical trial in patients with multiple myeloma, and OPN-2853, a potentially best-in-class BET bromodomain inhibitor, in a combination Phase 1 clinical trial with ruxolitinib in patients with myelofibrosis. Our novel, preclinical multi-functional degrader program is focused on targeting EP300/CBP and Ikaros/Aiolos for the treatment of multiple myeloma and lymphomas. The Opna team has a proven track record of scientific expertise and commercial value creation, having discovered and developed multiple drugs that have achieved FDA approval. For more information, please visit opnabio.com.

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