Opna Bio Announces Fast Track Designation Granted to OPN-6602 for the Treatment of Multiple Myeloma

OPN-6602 Currently Treating Patients in Phase 1 Clinical Trial

SOUTH SAN FRANCISCO, CA – April 15, 2026 – Opna Bio, a clinical-stage biopharmaceutical company focused on the discovery and development of novel oncology therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to OPN-6602, a dual EP300/CBP inhibitor, for the treatment of multiple myeloma (MM). The Fast Track designation applies to patients with relapsed/refractory MM who have received at least four prior lines of therapy.

OPN-6602 is an oral, small molecule inhibitor of EP300 and CREB-binding protein (CBP) currently in a Phase 1 clinical trial evaluating safety, tolerability, pharmacokinetics and preliminary clinical activity in patients with relapsed and/or refractory MM.

Multiple myeloma is a hematologic malignancy marked by the uncontrolled proliferation of plasma cells in the bone marrow, often leading to bone damage, kidney dysfunction and immune suppression. Despite therapeutic advances, most patients ultimately relapse or become refractory to available therapies, highlighting an unmet need for novel treatment options.

“Opna Bio has been a pioneer in the EP300/CBP inhibitor space and OPN-6602 was selected for its potency, selectivity, and optimized pharmacokinetic properties. We are encouraged by the progress of the study to date and look forward to reporting emerging clinical data at an upcoming scientific congress,” said Reinaldo Diaz, chief executive officer of Opna Bio.

The FDA’s Fast Track designation is designed to facilitate development and expedite review of therapies addressing serious conditions with unmet need. It offers benefits including more frequent FDA interactions, potential eligibility for accelerated approval and priority review, and rolling NDA submission. OPN-6602 was previously granted Orphan Drug Designation by the FDA in January 2025.

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 clinical development. The company is also advancing a novel preclinical multi-functional degrader program targeting EP300/CBP and Ikaros/Aiolos. Opna Bio's team has a proven track record of scientific innovation and value creation, having contributed to the discovery and development of multiple FDA-approved therapies. For more information, please visit opnabio.com.

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