



Piramal Pharma Solutions Announces Collaboration with BerGenBio on the Development of FDA Fast Track Designated Leukemia Treatment

- To develop bemcentinib, an AXL protein inhibitor for oncology with FDA Fast Track Designation status
- Will leverage the Piramal Pharma Solutions' (PPS) Xcelerate Integrated Solutions™ platform across its North America, Europe and India sites
- Selection of PPS is a validation of its integrated business model

Morpeth, UK, December 03, 2019: Piramal Enterprises Limited's Pharma Solutions business, a leading Contract Development and Manufacturing Organization (CDMO), today announced that the company will be partnering with BerGenBio ASA (OSE:BGBIO) on the development of bemcentinib for the treatment of elderly patients with relapsed Acute Myeloid Leukemia (AML). Bemcentinib was recently designated as a Fast Track drug by the U.S. Food and Drug Administration (FDA), as there are currently no marketed drugs specifically approved for relapsed AML patients, representing a significant unmet medical need.

According to **Peter DeYoung, CEO, Piramal Pharma Solutions**, "BerGenBio's decision to partner with us is a validation of our integrated business model. The breadth and scale of our assets and our expertise as a leading CDMO allow us to customize services according to their needs and deliver solutions that benefit the patients."

Richard Godfrey, Chief Executive Officer of BerGenBio, stated that "Outsourcing of development and manufacturing services is a requirement for us, and we were rigorous in our due diligence of potential partners. Piramal Pharma Solutions' capabilities — especially the Xcelerate Integrated Solutions platform — represent an ideal solution for BerGenBio."

To accelerate the timelines required for Fast Track development, PPS will be developing the drug leveraging its Xcelerate Integrated Solutions™ platform that delivers speed, flexibility and versatility to the drug development process. The Xcelerate platform, which addresses the industry's growing



need for preferred partner relationships, has been successfully applied to more than eighty programs.

Xcelerate Integrated Solutions[™] takes advantage of the extensive PPS network of drug discovery and development capabilities located across its sites in North America, Europe and India. Customers benefit from streamlined and fully integrated services, all managed by a single point of contact who expedites the exchange of information and accelerates timelines.

The bemcentinib development program encompasses a fully integrated program of PPS resources that includes intermediates sourced from India, pilot process development and API validation in North America and formulation development in Europe. As part of the partnership agreement, PPS is also expected to provide commercial manufacturing of the final drug product.

About Piramal Pharma Solutions:

Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies, Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs and Antibody Drug Conjugation. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.

www.piramalpharmasolutions.com

About Piramal Enterprises Ltd:

Piramal Enterprises Limited (PEL) is one of India's large diversified companies, with a presence in Financial Services, Pharmaceuticals and Healthcare Insights & Analytics. PEL's consolidated revenues were ~US\$1.9 billion in FY2019, with ~40% of revenues generated from outside India.

In Financial Services, Piramal Capital & Housing Finance Limited (PCHFL), a wholly-owned subsidiary of PEL, is registered as a housing finance company with the National Housing Bank (NHB) and offers a



complete suite of financial products, in both wholesale and retail financing across sectors. The Group has long-standing partnerships with leading institutional investors such as CPPIB, APG and Ivanhoé Cambridge, etc. IndiaRF, the distressed asset investing platform with Bain Capital Credit, invests in equity and/or debt across sectors (except real estate). PEL also has equity investments in the Shriram Group, a leading financial conglomerate in India.

In Pharma, through end-to-end manufacturing capabilities across 13 global facilities and a large global distribution network to over 100 countries, PEL sells a portfolio of niche differentiated pharma products and provides an entire pool of pharma services (including in the areas of injectable, HPAPI etc.). The Company is also strengthening its presence in the Consumer Product segment in India.

PEL's Healthcare Insights & Analytics business is the premier provider of healthcare analytics, data & insight products and services to the world's leading pharma, biotech and medical technology companies and enables them to take informed business decisions.

PEL is listed on the BSE Limited and the National Stock Exchange of India Limited in India.

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About AXL

AXL kinase is a cell membrane receptor and an essential mediator of the biological mechanisms underlying life-threatening diseases. In cancer, AXL suppresses the body's immune response to tumours and drives cancer treatment failure across many indications. AXL inhibitors, therefore, have potential high value at the centre of cancer combination therapy, addressing significant unmet medical needs and multiple high-value market opportunities. Research has also shown that AXL mediates other aggressive diseases.



About bemcentinib

Bemcentinib (formerly known as BGB324), is a potentially first-in-class selective AXL inhibitor in a broad phase II clinical development programme. Ongoing clinical trials are investigating bemcentinib in multiple solid and haematological tumours, as monotherapy and in combination with current and emerging therapies (including immunotherapies, targeted therapies and chemotherapy). Bemcentinib targets and binds to the intracellular catalytic kinase domain of AXL receptor tyrosine kinase and inhibits its activity. Increase in AXL function has been linked to key mechanisms of drug resistance and immune escape by tumour cells, leading to aggressive metastatic cancers.

About AML

Acute myeloid leukemia (AML) is the most common type of aggressive leukemia in adults, which has the lowest survival rate for all types of leukemia. In 2018, it is estimated there were nearly 20,000 new cases of AML diagnosed in the United States. Many AML patients older than age 60 are unable to tolerate intensive induction chemotherapy treatment.

About BerGenBio ASA

BerGenBio is a clinical-stage biopharmaceutical company focused on developing transformative drugs targeting AXL as a potential cornerstone of therapy for aggressive diseases, including immune-evasive, therapy resistant cancers. The company's proprietary lead candidate, bemcentinib, is a potentially first-in-class selective AXL inhibitor in a broad phase II oncology clinical development programme focused on combination and single agent therapy in lung cancer and leukaemia. A first-in-class functional blocking AXL antibody (BGB149) and an AXL-ADC (ADCT-601) are undergoing phase I clinical testing. In parallel, BerGenBio is developing a companion diagnostic test to identify those patient populations most likely to benefit from bemcentinib: this is expected to facilitate more efficient registration trials supporting a precision medicine-based commercialisation strategy.

BerGenBio is based in Bergen, Norway with a subsidiary in Oxford, UK. The company is listed on the Oslo Stock Exchange (ticker: BGBIO). www.bergenbio.com