News Release

Puma Biotechnology, Inc. Prevails Before European Patent Office Board of Appeals in Decision Upholding European Patent (EP 1848414) as Granted

LOS ANGELES, Calif., Dec. 2, 2020 – Puma Biotechnology, Inc. (NASDAQ: PBYI), a biopharmaceutical company, announced that it has prevailed in final appeal proceedings brought against its licensed European patent EP Patent 1848414, which covers the use of irreversible EGFR inhibitors in treating gefitinib and/or erlotinib resistant cancer and cancer with a T790M EGFR mutation. The European Board of Appeal announced its decision at a hearing on December 1st, rejecting the opposition of EP Patent 1848414 initiated by a Boehringer Ingelheim entity.

The EP Patent 1848414 originally granted in April 2011 covers the use of irreversible EGFR inhibitors in treating gefitinib and/or erlotinib resistant cancer and cancer with a T790M EGFR mutation. On November 28, 2011, an opposition was filed seeking invalidation of the patent. The Opposition Division of the European Patent Office issued a decision on February 4, 2014 revoking some claims but upheld a subset of the granted claims relating to a pharmaceutical composition for use in treating cancer in a subject having a T790M EGFR mutation without any modification. Both parties appealed that decision in 2017. At a final hearing, the Board of Appeals announced its decision, concluding that the opposition was inadmissible and reversing the European Opposition Division decision issued in 2014, thereby upholding the EP Patent 1848414 as originally granted.

About Puma Biotechnology

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. Puma in-licenses the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib, oral was approved by the U.S. Food and Drug Administration in 2017 for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, following adjuvant trastuzumab-based therapy, and is marketed in the United States as NERLYNX® (neratinib) tablets. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. NERLYNX was granted marketing authorization by the European Commission in 2018 for the extended adjuvant treatment of adult patients with early stage hormone receptor-positive HER2-overexpressed/amplified breast cancer and who are less than one year from completion of prior adjuvant trastuzumab-based therapy. NERLYNX is a registered trademark of Puma Biotechnology, Inc.

Further information about Puma Biotechnology may be found at www.pumabiotechnology.com.

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