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Press Release

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J-Pharma Announces FDA Orphan Drug Designation for JPH203 for the Treatment of  
Biliary Tract Cancer

J-Pharma Co., Ltd. (President & CEO: Masuhiro Yoshitake; Head Office: Tsurumi-ku, Yokohama, Kanagawa; hereinafter referred to as J-Pharma) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to JPH203 for the treatment of biliary tract cancer.

With this designation, J-Pharma will receive incentives such as seven years of marketing exclusivity in the U.S. upon regulatory approval, advisory consultation for clinical development programs, partial federal tax credit for clinical trial costs in the U.S., and waiver of application fees.

**About JPH203**

JPH203, J-Pharma's original small molecule, competitively inhibits amino acid binding pocket of L-type amino acid transporter (LAT1) by expressing on the cell membrane when cells, such as cancer cells, need huge amounts of energy due to rapid proliferation and/or activation. JPH203 is the first LAT1-targeted compound undergoing clinical studies and will become the first-in class medicine when approved by competent authorities. JPH203 is now undergoing a Phase 2 clinical study to treat advanced biliary tract cancer patients who are refractory or intolerant to standard chemotherapy. J-Pharm is also preparing the initiation of clinical program of JPH203 for the same indication in the U.S..

**About Biliary Tract Cancer**

Biliary tract cancer occurs in the intrahepatic bile ducts, extrahepatic bile ducts,

gallbladder, and duodenal papillary region, the passageways for bile. Approximately 8,000 cases of biliary tract cancer are diagnosed annually in the U.S., although the actual number of patients is thought to be a little higher due to the difficulty of diagnosis. Based on information obtained from the literature, we estimate the number of patients to be approximately 20,000. It is also reported that more than 20,000 people are newly diagnosed annually in Japan. Under such circumstances, there are currently only limited treatment options for biliary tract cancer, and there is a worldwide need for new therapeutic agents.

J-Pharma will continue our efforts to bring JPH203 to market for patients as soon as possible.