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Intezyne Technologies Granted Orphan Drug Designation for IT-139 in Pancreatic Cancer

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Intezyne Technologies, Inc. →
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TAMPA, Fla., June 20, 2017 /PRNewswire/ -- Intezyne Technologies, a clinical-stage biopharmaceutical company developing novel anti-cancer therapies, announced that that the Office of Orphan Products Development of the Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to IT-139, the most clinically advanced GRP78 inhibitor in development for solid tumors, for the treatment of pancreatic cancer. The FDA's Orphan Drug program provides numerous benefits to support development of promising drugs for rare diseases, including 7-year post-approval market exclusivity, FDA assistance in protocol design, and an exemption from PDUFA fees.

"Our receipt of an Orphan Drug Designation for IT-139 in pancreatic cancer is an exciting regulatory milestone for Intezyne and a critical step towards clinical advancement of this promising first-in-class therapy addressing an unmet need," stated Dr. Carolyn Paradise, Intezyne's Chief Medical Officer. "Pancreatic cancer is currently the fourth most common cancer in the U.S., with approximately 54,000 new diagnoses annually, the majority of which are diagnosed only after their cancer has spread locally and/or metastasized to distant organs. Sadly, pancreatic cancer has proven extremely difficult to treat, with 1-year and 5-year survival rates of only 20% and 8%, respectively – rates which we hope to improve with IT-139."

The Company's previously completed Phase 1 monotherapy trial of IT-139 showed that it was well-tolerated, with manageable side effects, and successfully demonstrated anti-tumor activity in numerous tumor types. Preclinical studies have shown IT-139's synergy in combination with various other anti-cancer agents including taxanes, platinums, and gemcitabine – the typical first-line therapies for patients with locally advanced or metastatic pancreatic cancer.

Dr. Suzanne Bakewell, Vice President and Program Manager for IT-139 added, "Since completing our Phase 1 monotherapy trial of IT-139, we have been working with academic collaborators to fully characterize IT-139's mechanism of action (MOA) – efforts which have yielded exciting results thus far. IT-139 downregulates the stress-induction of GRP78 in cancer cells, a critical cell survival protein that is associated with both drug resistance and tumor proliferation. GRP78 expression is not elevated in the same way in normal cells, leaving them unaffected."

Dr. Kevin Sill, CEO of Intezyne, commented, "Intezyne is currently completing cGMP manufacturing for IT-139 in anticipation of initiating one or more combination Phase 1b/2a studies in 2018. The synergy with low toxicity observed preclinically in combination with existing anti-cancer agents has already generated considerable attention from both investors and potential strategic partners, a number of whom Russell and I will be meeting this week at the 2017 BIO International meeting in San Diego."

For more information, please visit the Company's website at www.intezyne.com.

Contact:
E. Russell McAllister, CFO
164938@email4pr.com, (813) 910-2120