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Intezyne Technologies Initiates First-In-Human Trials for Topoisomerase-1 Inhibitor IT-141; GRP78 Inhibitor IT-139 to be Featured in AACR Symposium

TAMPA, Fla., March 31, 2017 /PRNewswire/ -- Intezyne Technologies, a clinical-stage biopharmaceutical company developing novel anti-cancer therapies, announced that it has initiated first-in-human trials for its topoisomerase-1 inhibitor, IT-141, which encapsulates SN-38, the active metabolite of Pfizer's Camptosar® (*irinotecan*) and Merrimack Pharmaceuticals' Onivyde® (*liposomal irinotecan*), within a proprietary tumor-targeting micelle nanoparticle.

Unlike both Camptosar® and Onivyde®, IT-141 does not require metabolic generation of the active derivative, SN-38, delivering up to 50x more SN-38 to the tumor than Camptosar® in preclinical models. Despite inefficient delivery (less than 4% of irinotecan successfully converts into SN-38, of which only a fraction reaches the tumor), Camptosar® was one of Pfizer's blockbuster products, generating sales of more than $1 billion annually and remains on the World Health Organization (WHO) List of Essential Medicines.

Dr. Carolyn Paradise, Intezyne's Chief Medical Officer, stated, "We are excited to enter the clinic with IT-141, and I look forward to working closely with the investigators. Based on both the anti-tumor activity observed in established preclinical models and the potential safety advantages provided by Intezyne's proprietary tumor-targeting delivery technology, IT-141 has the potential to significantly improve patient outcomes across a wide variety of solid tumor indications where Camptosar® or Onivyde® are currently used."

On April 3, Intezyne's IT-139, a novel GRP78 inhibitor and the most clinically advanced GRP78 inhibitor in development for solid tumors, will be featured in an American Association for Cancer Research (AACR) symposium, "The Unfolded Protein Response in Tumor Biology: GRP78/BiP: Cancer's Comrade in Crime," presented by Dr. Amy S. Lee, PhD of the University of Southern California (USC). The Company's previously completed Phase 1 trial of IT-139 showed that it was well-

tolerated, with manageable side effects, and successfully demonstrated anti-tumor activity in numerous tumor types. The 2017 AACR meeting will be attended by Mr. E. Russell McAllister, Intezyne's CFO, Dr. Paradise, and Dr. Suzanne Bakewell, Vice President and Program Manager for IT-139.

Mr. McAllister stated, "Having followed Intezyne's progress for the past few years, I was excited to join the management team last fall to help drive development of several potentially revolutionary therapeutic agents. GRP78 has been shown to play a significant role in tumor resistance and survival, and IT-139 has shown surprising synergy with existing anti-cancer agents, including checkpoint inhibitors. Consequently, after completing cGMP manufacturing in 2017, we intend to initiate one or more Phase 1b/2a studies in early 2018 to further explore these synergies."

"This is an exciting time for Intezyne as we continue to advance our lead product candidates. Our risk-mitigated development strategy requires that we aggressively strengthen the Company from both a financial and human capital standpoint," said Dr. Kevin Sill, Intezyne's Founder and CEO. "Russell brings tremendous development, financial and strategic expertise to Intezyne, and we expect that he will be instrumental in optimally positioning the Company for success as we move into mid-stage clinical studies for IT-139 and IT-141 and raise additional capital from investors."

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

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