BDD Pharma Ltd

For immediate release – 07 Sep 2018

BDD Pharma and Cingulate Therapeutics announce license agreement with OralogiK™ enabled triple pulse products

BDD Pharma, a privately-owned drug delivery company specializing in the development of modified and controlled release oral formulations, and Cingulate Therapeutics, a clinical stage biopharmaceutical company, today announced that the companies have completed a license agreement for BDD's OralogiK™ timed drug delivery technology. The agreement, which includes an upfront payment, milestones and future royalties, relates to the development of CTx-1301 and CTx-1302 for the treatment of ADHD. The companies have been operating under a license option agreement since 2016.

The completion of the agreement follows a successful clinical proof of concept study performed at BDD's facilities in Glasgow, UK which demonstrated that Cingulate's therapy CTx-1301, utilizing OralogiK™ technology, delivered consistent tri-modal release of the dexmethylphenidate hydrochloride (d-MPH), and extended d-MPH blood plasma levels when compared to Focalin® XR's bi-phasic release of d-MPH.

BDD's proprietary OralogiK™ technology provides unrivalled control of drug release *in vivo* – delivery at the right place and the right time. OralogiK™ enables the delivery of single, multi-dose or drug combinations at pre-determined times post dose. Potential uses include scientifically targeted "re-design" of the delivery of new and existing drugs. The intellectual property surrounding the OralogiK™ proprietary technology is protected by key patents in the major markets worldwide.

BDD is uniquely equipped to assist our customers research and development goals through the provision of targeted formulation development utilizing

OralogiK™, clinical batch manufacture and accelerated clinical assessment at our on-site clinical unit in Glasgow, UK.

Dr Carol Thomson, CEO of BDD, said:
"We are delighted to be working with Cingulate Therapeutics on these projects; both CTx-1301 and CTx-1302 medications will be exciting additions to the ADHD market, made possible in large part by BDD's OralogiK™ technology"

Shane J. Schaffer, PharmD, Chairman and CEO of Cingulate Therapeutics, said, *"The completion of this licensing agreement along with our successful collaboration on the Proof of Concept study present an encouraging foundation for this and future licensing agreements. Securing this license provides additional IP protection for our lead candidates which incorporate immediate, delayed and sustained release deliveries of medication in a single tablet intended to deliver the right dose at the right time for ADHD patients."*

BDD and Cingulate Therapeutics will continue to expand their relationship with the development of additional novel products in the near future.

Ends 07 Sep 2018

Further enquiries:

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Notes to Editors

About BDD
BDD Pharma Ltd is a privately-owned drug delivery company specializing in the development of modified and controlled release oral formulations. BDD's OralogiK™ technology is a tablet-in-tablet drug delivery system providing timed release, sustained release and the opportunity for complex bi- and tri-phasic release of one or multiple drugs. The OralogiK™ technology is protected with granted patents in the US, EU and Japan. Supported by investment from Archangels and the Scottish Investment Bank, BDD has in house clinical trial

capabilities for the conduct of gamma scintigraphic/ pharmacokinetic studies in humans.

For more information visit www.bddpharma.com.

About Cingulate Therapeutics

Cingulate Therapeutics LLC is a privately held clinical stage biopharmaceutical company focused on the development of new and innovative products utilizing the formulation and manufacture of once-daily tablets of multi-dose therapies, with an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). Cingulate is developing two proprietary, first-line stimulant medications, CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine), for the treatment of ADHD intended for all patient segments: children, adolescents, and adults. CTx-1301 and CTx-1302 utilize an innovative, flexible core tableting technology with a Target Product Profile designed to deliver a rapid onset and last the entire active day while providing a controlled descent of plasma drug levels to optimize treatment. The Company has completed a Proof of Concept Phase I clinical trial and plans to implement the full clinical plan for both CTx-1301 and CTx-1302 in 2018. Cingulate anticipates filing INDs for both assets in the third and fourth quarters of 2018 and will pursue approval via the accelerated 505(b)(2) regulatory pathway. The company has offices in Kansas City, KS and Morristown, NJ, USA. For more information visit www.cingulatetherapeutics.com