[364] THE ACCORDION PILL A UNIQUE ORAL DELIVERY PLATFORM TO ENHANCE PHARMACOKINETICS AND THERAPEUTIC BENEFIT OF CHALLENGING DRUGS

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Investment Rational

Intec Pharma's Accordion Pill® (AP) is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention and specific release mechanism. Intec is conducting a global Phase 3 clinical study of AP-Carbidopa/Levodopa (AP-CD/LD) for the treatment of Parkinson's disease symptoms – a multi-billion dollar market.

Business Strategy

Intec uses its AP technology to advance known compounds through the 505b2 regulatory path to approval, with plans to partner these for commercialization. Intec also works in collaboration with companies, such as Novartis, to develop APs for proprietary drugs. In addition, the Company will partner to develop APs that can enhance the lifecycle management of the partners' currently marketed drugs.

Core Technology

With AP, drug is released slowly in the stomach over hours, allowing the body to absorb it more steadily. When the pill is done, it simply dissolves in the GI tract. This novel drug delivery system can improve PK, allows for high drug loading and is ideally suited for compounds with a narrow absorption window, poorly soluble drugs and/or drugs with poor bioavailability.

Product Profile/Pipeline

Intec's product pipeline includes two product candidates in clinical trial stages: AP-CD/LD, in Phase 3 development for the treatment of Parkinson's disease symptoms, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for various indications including low back neuropathic pain and fibromyalgia.

What's Next?

Intec's R&D program includes the completion of enrollment of the Phase 3 Accordance trial in Parkinson's disease, initiation of Phase 1 Accordion Pill studies of CBD, THC and the combination of both; completion of a Phase 1 pharmacokinetics (PK) study of 500 mg AP-CD/LD 3x a day (TID); and initiation of validation studies of the Company's commercial manufacturing machine.