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# Addressing critical unmet healthcare needs

**D&D Pharmatech funds the development of innovative therapeutic and diagnostic solutions to address critical unmet medical needs. D&D subsidiary Theraly Fibrosis is developing a novel treatment for chronic pancreatitis and other fibrotic indications, TLY012. Neuraly, another D&D subsidiary, recently launched a phase 2 study in Parkinson disease.**

Clinical-stage global biotech company D&D Pharmatech was founded with a mission to drive the development of novel medicines through disease-specific subsidiary companies founded by a top-tier medical research faculty. This corporate structure allows D&D Pharmatech to accelerate the translation of cutting-edge research into lifesaving therapeutic products for patients.

D&D Pharmatech has assembled a pipeline of clinical-stage investigational medicines through licensing agreements with leading academic research centers. Since its founding in 2014, D&D Pharmatech has established four subsidiaries in the USA—Theraly Fibrosis, Inc., Neuraly, Inc., Precision Molecular, Inc. and Valted Seq, Inc.—and is continually looking for new opportunities to source innovative solutions.

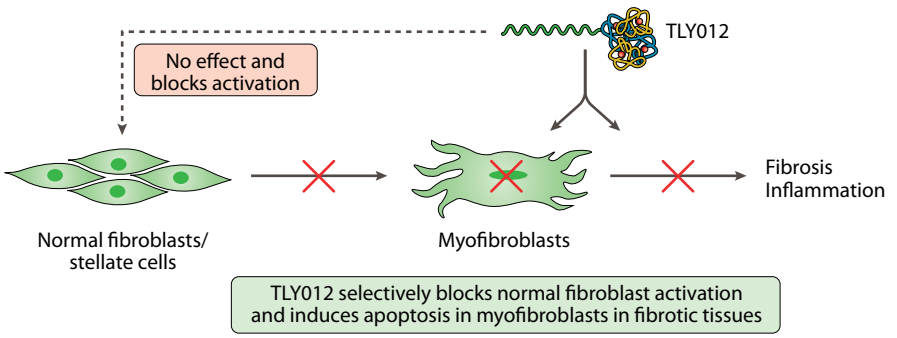


**Fig. 1 | Blazing a TRAIL in fibrotic disease.** Theraly's lead product candidate is TLY012, a recombinant version of the human TRAIL protein that selectively targets myofibroblasts (MFBs) involved in fibrosis. Reversing fibrosis has the potential to cure fibrotic diseases such as systemic sclerosis, liver fibrosis or cirrhosis.

## A new TRAIL for fibrotic disease

Theraly Fibrosis' lead development program centers on human tumor necrosis factor (TNF)-related apoptosis-inducing ligand (TRAIL). TRAIL helps remove myofibroblasts—the key contributors to fibrotic disease—and blocks de novo conversion of normal fibroblasts into those driving fibrosis regardless of tissue type[1] (Fig. 1). Because of this, TLY012, Theraly's proprietary version of TRAIL, has the potential to be a first-in-class treatment for a range of fibrotic diseases, including chronic pancreatitis, non-alcoholic steatohepatitis (NASH), liver fibrosis, liver cirrhosis and systemic sclerosis.

TRAIL has been studied as a therapeutic over the past 20 years, primarily as a potential treatment for cancer. However, soluble recombinant TRAIL has a short half-life and is not very stable. TLY012 is more stable and has a greatly increased circulating half-life. The company is first developing TLY012 for chronic pancreatitis, an incurable fibrotic disease characterized by chronic pain and progressive fibrosis that damages the pancreas and results in the loss of endocrine and exocrine function. In September 2019, TLY012 obtained orphan drug designation from the US Food and Drug Administration for the treatment of chronic pancreatitis, and Theraly is planning to initiate phase 1 clinical studies in late 2020.

Theraly's goal is to further develop TLY012 as a therapy for other major fibrotic diseases. The market for liver fibrosis—the largest target market for TLY012—alone is growing at high double-digit annual rates globally. "We are planning to carry TLY012 through end of phase 2 and are seeking an option-based partnership to support this effort," said Joshua Yang, head of business development and corporate strategy. "In addition, we are pursuing parallel clinical development for multiple indications of TLY012."

## A total care system for neurodegenerative diseases

Neuraly, Precision Molecular and Valted Seq are each tackling neurodegenerative diseases by addressing a major need in the field: developing novel therapeutic agents, advancing powerful imaging platforms and analyzing genetic data to improve diagnosis and disease monitoring, respectively.

Neuraly's lead compound is NLY01, a potent, long-acting glucagon-like peptide 1 receptor (GLP1R) agonist. NLY01 inhibits activation of microglial cells in the brain, limiting neuroinflammation and neurodegeneration in Parkinson disease (PD)[2] and Alzheimer disease (AD) and potentially other diseases. Neuraly started a phase 2 proof-of-concept clinical trial with NLY01 in PD in February 2020 and is planning a phase 2 in AD in Q4 2020.

Precision Molecular is advancing four clinical stage imaging agents and one investigational new drug (IND)-enabling PET imaging agent for early detection and management of neuroinflammation in AD and PD. Precision Molecular's imaging agent PMI04 targets proteins expressed in activated microglia and proteins involved in neuroinflammation, providing a non-invasive approach to quantifying neuroinflammation[3]. These products are ideal companion diagnostics for medications such as NLY01 and as independent tests to help identify patients with early-stage or asymptomatic disease. The company received an investment from the Alzheimer's Drug Discovery Foundation and researchers who are working on the agents received additional funding from the Michael J. Fox Foundation.

Valted Seq is developing the world's largest collection of single-cell information derived from diseased post-mortem brain tissues. This unprecedented collection of big data related to neuroinflammation will be invaluable for identifying biomarkers for targeted therapy and early diagnosis of neurodegenerative diseases. According to Seulki Lee, Founder and Chairman of D&D Pharmatech, "Precision Molecular and Valted Seq will play critical roles in the development of diagnostic technologies to be used together with Neuraly's pipeline and other innovative technologies. The resulting synergy supports the companies' paradigm of total care, 'early diagnosis—early treatment'."

## Flexible partnering for innovations

Following a successful Series B financing round worth $137.1 million, the clinical programs of D&D Pharmatech's companies are completely funded to date at this point. The company has more than 70 employees and an experienced R&D team leading multiple clinical studies and identifying new drug candidates to expand its pipeline.

"We are constantly evaluating new candidates for development and business collaborations to continue fulfilling our mission of developing innovative drugs to address critical unmet medical needs," said Yang.

1. Park, J.-S. et al. *Nat. Commun.* **10**, 1128 (2019).
2. Yun, S. P. et al. *Nat. Med.* **24**, 931 (2018).
3. Horti, A. G. et al. *Proc. Natl Acad. Sci. USA* **116**, 1686 (2019).

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