

Zydus files IND application with the USFDA for 'ZYT1' a novel candidate to treat dyslipidemia

Ahmedabad, April 02, 2009

Zydus Cadila, a global healthcare provider and one of India's leading healthcare companies, announced the filing of the IND application for ZYT1 - a novel lipid lowering molecule with the USFDA. Designed and developed at the Zydus Research Centre, ZYT1 is a novel, anti-dyslipidemic agent which may provide an alternative to statins or be an add-on to statin therapy.

Dyslipidemia is a clinical condition characterized by an elevation of cholesterol and/or triglycerides in the bloodstream. Over 80% of patients with coronary heart disease, even those currently on medication, remain above the targeted levels for cholesterol.

Heart disease accounts for approximately 17 million deaths annually. Cardiovascular segment is the largest therapeutic segment in the world pharmaceutical market and treatment of dyslipidemia represents a major sector of this market, which is expected to grow from \$36 billion in 2007 to \$42 billion in 2012.

Speaking on the new development, Mr. Pankaj Patel, Chairman and Managing Director, Zydus Cadila, said, "This is an important milestone in the new drug discovery initiatives that are being undertaken at the Zydus Research Centre. With ZYT1 entering the Phase 1 clinical trials, it holds promising commercial potential as a future blockbuster due to unmet medical needs and absence of effective treatments in dyslipidemia patients."

The group has already filed an IND for ZYT1 in India and is currently in Phase 1 clinical trials. ZYT1 has demonstrated beneficial effect on LDL-cholesterol and triglycerides, comparable to the effects seen with statins. When combined with statins, ZYT1 exhibited a pronounced effect in lowering LDL-cholesterol and triglycerides with the added benefit of a very high margin of safety.

The group has a strong research pipeline of 6 NMEs in various stages of clinical trials of which, five NMEs are targeted at cardiometabolic disorders. The NME - ZYH1, for treating dyslipidemia has completed Phase II clinical trials successfully. ZYH2, the novel agent for treating diabetes is undergoing Phase I trials. ZYI1, the anti-inflammatory and pain management compound is currently in Phase II clinical trials. ZYO1, a novel drug candidate for treating obesity and related disorders has completed Phase I clinical trials. ZYH7, a novel drug candidate for treating dyslipidemia and metabolic disorders and ZYT1, a novel drug candidate for treating dyslipidemia are in Phase 1 clinical trials.

The Zydus Research Centre has over 20 discovery programmes ongoing with several candidates in the pre-clinical development stage focused on metabolic, cardiovascular, pain and inflammation therapeutic areas. With over 375 research professionals spearheading its NME research programme, Zydus has in-house capabilities to conduct discovery research from concept to IND enabling pre-clinical development and human proof-of-concept clinical trials.

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