

ABOUT THIS REPORT•PharmaVitae Explorer database

EXECUTIVE SUMMARY•Catalysts

PDUFA DATES•Regeneron•Zaltrap: PDUFA – August 4

•Eylea: PDUFA – September 21

•Salix•Crofelemer: PDUFA – September 5

•Ironwood•Linaclotide: PDUFA – September 8

•Linaclotide clinical trials

•NPS Pharmaceuticals•Gattex PDUFA – September 28

•Gattex should win approval based on positive Phase III data and CHMP positive opinion

•Amylin•Metreleptin: PDUFA – October 3

•Ultra-rare nature of lipodystrophy lowers bar for approval

•Santarus•Uceris: PDUFA – October 16

•Uceris clinical trials

•United Therapeutics•Oral treprostinil: PDUFA – October 26

•Medivation•Enzalutamide: PDUFA – November 21

•Onyx•Regorafenib: PDUFA – November 23

•Positive data make approval likely, but uptake may be low

•Exelixis•Cabozantinib: PDUFA – November 29

•Cabozantinib looks likely to be approved based on strong Phase III data

PHASE III TRIAL RESULTS•ArQule: tivantinib – non-small cell lung cancer•Tivantinib: Phase III results – H2 2012

•Interim analysis of MARQUEE trial expected in H2 2012

•BioMarin: Firdapse – Lambert-Eaton myasthenic syndrome •Firdapse Phase III results – H2 2012

•Phase III LMS-002 trial

•BioMarin: GALNS – mucopolysaccharidosis IVA •GALNS Phase III results – H2 2012

•Phase II trials

•Phase III trial

•Elan: bapineuzumab – Alzheimer's disease•Bapineuzumab Phase III results – H2 2012

•Phase II trials

•Phase III trials

•Rigel: fostamatinib – rheumatoid arthritis•Fostamatinib Phase III results – H2 2012

•Phase III program: OSKIRA and head-to-head clinical trials

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