

Pharmaceutical Business

Clinical Development as of May 1, 2018

<In-house development>

Code (Generic Name)	Potential Indication/Dosage form	Mechanism		Phase	Note
JTZ-951 (enarodustat)	Anemia associated with chronic kidney disease /Oral	HIF-PH inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis- stimulating hormone, via inhibition of HIF-PHD.	Phase3(Japan) Phase1(Overseas)	In-house Co-development with Torii
JTE-052 (delgocitinib)	Autoimmune/allergic diseases /Oral, Topical *Atopic dermatitis/Topical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	Phase3(Japan)	In-house *Co-development with Torii
JTE-051	Autoimmune/allergic diseases /Oral	Interleukin-2 inducible T cell kinase inhibitor	Suppresses overactive immune response via inhibition of the signal to activate T cells related to immune response.	Phase2(Overseas)	In-house
JTT-251	Type 2 diabetes mellitus /Oral	PDHK inhibitor	Decreases blood glucose by activation of pyruvate dehydrogenase (PDH) related to carbohydrate metabolism.	Phase1(Overseas)	In-house
JTK-351	HIV infection /Oral	HIV integrase inhibitor	Suppresses blood HIV levels by inhibiting the activity of integrase, an enzyme involved in the replication of HIV.	Phase1(Japan)	In-house
JTE-451	Autoimmune/allergic diseases /Oral	ROR γ antagonist	Suppresses overactive immune response via inhibition of ROR γ related to Th17 activation.	Phase1(Overseas)	In-house
JTS-661 (serlopitant)	Pruritus/Oral	NK-1receptor antagonist	Suppresses pruritus involving the neurokinin (NK-1) receptor antagonist signalling pathway.	Phase2(Japan)	In-license (Menlo Therapeutics) Co-development with Torii *Phase2 study discontinued
JTT-751 (ferric citrate)	Iron-deficiency anemia/Oral	Oral iron replacement	Corrects iron-deficiency anemia by using absorbed iron for synthesis of hemoglobin.	Phase2(Japan)	In-license (Keryx Biopharmaceuticals) Co-development with Torii Additional indication

Clinical trial phase presented above is based on the first dose.

<Licensed compounds>

Compound (JT's code)	Licensee	Mechanism		Note
trametinib	Novartis	MEK inhibitor	Inhibits cellular growth by specifically inhibiting the activity of MAPK/ERK pathway.	Marketing application submitted (trametinib+dabrafenib) for melanoma(adjuvant) with BRAF V600E/K mutation in US and BRAF V600 mutation in EU
Anti-ICOS monoclonal antibody	MedImmune	ICOS antagonist	Suppresses overactive immune response via inhibition of ICOS which regulates activation of T cells.	
JTE-052	LEO Pharma ROHTO Pharmaceutical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	
JTZ-951	JW Pharmaceutical	HIF-PH inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis- stimulating hormone, via inhibition of HIF-PHD.	

Updates since the previous announcement on February 6, 2018:

<In-house development>

•JTS-661: Phase2 study discontinued, examining the future development policy.

<Licensed compounds>

•JTE-052: Licensed exclusive rights to ROHTO Pharmaceutical for further development and marketing JTE-052 in Japan for the treatment of the specific disease(es) in ophthalmology. (March 15, 2018)

•trametinib: Novartis Pharma K.K. announced that Mekinist® (trametinib) has approved in Japan, in combination with Tafinlar® (dabrafenib), for the treatment of BRAF mutant non-small cell lung cancer (NSCLC). (March 23, 2018) *additional indication