

Pharmaceutical Business

Clinical Development as of October 30, 2020

<In-house development>

Code (Generic Name)	Potential Indication/Dosage form	Mechanism		Phase (Region)	Origin	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-PH.	Phase1 (Overseas)	In-house	• Co-development with Torii
JTE-052 (delgocitinib)	Atopic dermatitis (pediatric) /Topical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	NDA filed (Japan)	In-house	• Co-development with Torii
	Atopic dermatitis (infant) /Topical			Phase3 (Japan)		• Co-development with Torii
	Autoimmune/allergic diseases /Oral, Topical			Phase1 (Japan)		
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	
JTE-451	Autoimmune/allergic diseases /Oral	ROR γ antagonist	Suppresses overactive immune response via inhibition of ROR γ related to Th 17 activation.	Phase2 (Overseas)	In-house	
	Autoimmune/allergic diseases /Topical			Phase1 (Japan)		
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	
JTT-662	Type 2 diabetes mellitus /Oral	SGLT1 inhibitor	Suppresses postprandial hyperglycemia and normalizes blood glucose level via inhibition of SGLT1.	Phase1 (Overseas)	In-house	
JTE-761	Autoimmune/allergic diseases /Oral	ROR γ antagonist	Suppresses overactive immune response via inhibition of ROR γ related to Th 17 activation.	Phase1 (Overseas)	In-house	
JTT-751 (ferric citrate hydrate)	Iron-deficiency anemia/Oral	Oral iron replacement	Corrects iron-deficiency anemia by using absorbed iron for synthesis of hemoglobin.	NDA filed (Japan)	In-license	• Licensed from Keryx Biopharmaceuticals • Co-development with Torii • Additional indication

- Clinical trial phase presented above is based on the first dose.
- We are also conducting additional studies to examine the potential for use in additional dosage forms.

<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.	
Anti-ICOS monoclonal antibody	AstraZeneca	ICOS antagonist	Suppresses overactive immune response via inhibition of ICOS which regulates activation of T cells.	
delgocitinib	LEO Pharma ROHTO Pharmaceutical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	
enarodustat	JW Pharmaceutical Salubris	HIF-PH inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis-stimulating hormone, via inhibition of HIF-PH.	

Updates since the previous announcement on July 31, 2020:

- JTZ-951: Manufacturing and Marketing Approval of ENAROY[®] Tablets 2 mg·4 mg for the Treatment of Anemia Associated with Chronic Kidney Disease in Japan (September 25, 2020)
- JTE-052(Infants) : advanced to Phase3 in Japan