Pharmaceutical Business
Clinical Development as of July 31, 2019

＜In-house development＞

Code (Generic Name)	Potential Indication/Dosage form	Mechanism		Phase (Region)	Note
JTE-052 (delgocitinib)	Atopic dermatitis/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 *Pediatric：Phase3 (In-house)
	Autoimmune/allergic diseases /Oral, Topical			Phase1 (Japan)	In-house
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.	Phase3 (Japan) Phase1 (Overseas)	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
JTE-451	Autoimmune/allergic diseases /Oral	RORγ antagonist	Suppresses overactive immune response via inhibition of RORγ related to Th17 activation.	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
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
JTT-751 (ferric citrate hydrate)	Iron-deficiency anemia/Oral	Oral iron replacement	Corrects iron-deficiency anemia by using absorbed iron for synthesis of hemoglobin.	Phase3 (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.	
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	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 April 26, 2019:
None

(Reference)
・JTT-751(Additional indication):
JT and Torii announced the top-line results of the pivotal Phase 3 comparative study in adult patients with iron deficiency anemia (IDA) in Japan.
The top-line results show that the study met the primary endpoint by establishing non-inferiority of JTT-751 compared with a control drug in the changes in hemoglobin level from baseline at week 7. JTT-751 showed a favorable tolerability profile on safety within the treatment period. (July 9, 2019)
https://www.jt.com/media/news/2019/pdf/20190709_E01.pdf

・JTZ-951:
JT and Torii announced the top-line results of two pivotal Phase 3 comparative studies in anemic patients with non-dialysis dependent chronic kidney disease (NDD-CKD) or hemodialysis dependent CKD (HDD-CKD) on erythropoiesis stimulating agent (ESA) therapy for JTZ-951.
The top-line results show that the differences in mean hemoglobin at week 20, 22 and 24 achieved the non-inferiority criterion and both studies met the primary endpoints. Furthermore, the favorable tolerability profile on safety of JTZ-951 was obtained during the studies. (July 12, 2019)
https://www.jt.com/media/news/2019/pdf/20190712_E01.pdf