Japan Tobacco Inc. Clinical Development as of February 6, 2018

＜In-house development＞

Code （Generic Name）	Potential Indication/Dosage form	Mechanism		Phase	Note
JTZ-951	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	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	RORγ antagonist	Suppresses overactive immune response via inhibition of ROR γ related to Th 17 activation.	Phase1(Overseas)	In-house
JTS-661（serlopitant）	Pruritus/Oral	NK-1antagonist	Suppresses pruritus involving the neurokinin (NK-1) receptor antagonist signalling pathway.	Phase2(Japan)	In-license （Menlo Therapeutics） Co-development with Torii
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.	NSCLC with BRAF V600E mutation, trametinib+dabrafenib Japan marketing application submitted Melanoma(adjuvant) with BRAF V600E/K mutation, trametinib+dabrafenib U.S. marketing application submitted
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	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 November 1, 2017:

＜In-house development＞
・JTZ-951 advanced to Phase 3 in Japan.
・JTS-661 has entered the clinical trial stage (Phase2) in Japan.

＜Licensed compounds＞
・Novartis announced on December 22, 2017 that Mekinist® (trametinib) has filed NDA in U.S, in combination with Tafinlar® (dabrafenib) for the adjuvant treatment of stage 3 BRAF V600E/K mutation-positive melanoma. *additional indication