Japan Tobacco Inc. Clinical Development as of May 2, 2016

＜In-house development＞

Code （Generic Name）	Potential Indication/Dosage form	Mechanism		Phase	Note
JTK303(elvitegravir)/ cobicistat/emtricitabine/ tenofovir alafenamide fumarate	HIV infection /Oral	HIV integrase inhibitor/ Nucleoside reverse transcriptase inhibitor	Suppresses blood HIV levels by inhibiting the activities of integrase and reverse transcriptase, enzymes involved in the replication of HIV.	NDA filed (Japan)	JTK-303(elvitegravir); In-house Cobicistat, Emtricitabine, Tenofovir Alafenamide; In-license (Gilead Sciences)
emtricitabine/ tenofovir alafenamide fumarate	HIV infection /Oral	Nucleoside reverse transcriptase inhibitor	Suppresses blood HIV levels by inhibiting the activity of reverse transcriptase, an enzyme involved in the replication of HIV.	Preparing to file (Japan)	In-license (Gilead Sciences)
JTT-851	Type 2 diabetes mellitus /Oral	G protein-coupled receptor 40 agonist	Decreases blood glucose by stimulation of glucose-dependent insulin secretion.	Phase2 (Japan) Phase2 (Overseas)	In-house
JTZ-951	Anemia associated with chronic kidney disease /Oral	HIF-PHD inhibitor	Increases red blood cells by stimulating production of erythropoietin, an erythropoiesis-stimulating hormone, via inhibition of HIF-PHD.	Phase2(Japan) Phase1(Overseas)	In-house
JTE-052	Autoimmune/allergic diseases /Oral, Topical	JAK inhibitor	Suppresses overactive immune response via inhibition of Janus kinase (JAK) related to immune signal.	Phase2(Japan)	In-house
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.	Phase1(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

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 Kinase (MEK1/2).	
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.	

Updates since the previous announcement on February 4, 2016:

＜In-house development＞
・elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) : filed NDA for marketing approval in Japan (March 4, 2016)
・JTE-151: terminated

＜Licensed compounds＞
・ Mekinist (trametinib):
Novartis Pharma K.K. announced Mekinist has been approved in Japan, in combination with Tafinlar (dabrafenib), for the treatment of unresectable
BRAF V600 mutation-positive malignant melanoma. (March 28, 2016)