

## US FDA approvals tracker: September



[Joanne Fagg](#)

The biggest approval of last month was Novo's oral semaglutide, now branded Rybelsus; however, questions remain over its price tag and whether it can get a label for cardiovascular risk reduction ([Pricing questions remain as Novo gets the nod for oral sema, September 23, 2019](#)). Meanwhile Ardelyx gained its first ever approval with Ibsrela in constipation-predominant irritable bowel syndrome, but the product's commercial chances could depend on Ardelyx hooking a partner. The US FDA also had a busy month for supplementary approvals. Notably Johnson & Johnson's Invokana [became the first SGLT2 inhibitor approved for reducing cardiorenal events in patients with type 2 diabetes and chronic kidney disease](#), based on the Credence study. However, Roche's Tecentriq will have to wait a bit longer, with its decision in first-line NSCLC delayed until December.

### Notable first-time US approval decisions in September

Project	Company	Product NPV (\$m)*	Outcome
Rybelsus (oral semaglutide)	Novo Nordisk	5,126	Approved
Ibsrela (tenapanor)	Ardelyx	1,593	Approved
Jynneos (Imvamune/MVA-BN)	Bavarian Nordic	1,276	Approved
Gvoke HypoPen	Xeris Pharmaceuticals	664	Approved
Valtoco	Neurelis	-	No decision yet

\*NPV data as of September 30, EvaluatePharma. Source: [Go or no go? Novo awaits call on oral sema, August 30, 2019](#).

### Supplementary and other notable approval decisions in September

Product	Company	Event type	Outcome
Tecentriq	Roche	sBLA for 1L NSCLC (plus Abraxane and carboplatin)	Delayed to December 2
Ofev	Boehringer Ingelheim	sNDA for systemic sclerosis-associated interstitial lung disease	Approved
Nucala	Glaxosmithkline	sBLA as add-on treatment for eosinophilic asthma in pts aged 6-11	Approved

Supplementary and other notable approval decisions in September			
Pifeltro	Merck & Co	sNDA for HIV-1 pts switching from stable antiretroviral regimen	Approved
Delstrigo	Merck & Co	sNDA for HIV-1 pts switching from stable antiretroviral regimen	Approved
Darzalex	Johnson & Johnson/Genmab	sBLA for 1L MM pts eligible for stem cell transplant (plus Velcade, thalidomide, dexamethasone)	Approved
Invokana	Johnson & Johnson	sNDA for chronic kidney disease in type 2 diabetics	Approved
Keytruda + Lenvima*	Merck & Co, Eisai	sBLA for endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient	Approved
Erleada*	Johnson & Johnson	sNDA in metastatic castration-sensitive prostate cancer	Approved
Mavyret*	Abbvie	sNDA for eight-week treatment for adults and children with all genotypes of hepatitis C	Approved
Rituxan*	Roche	sBLA for granulomatosis with polyangiitis and microscopic polyangiitis in children two years of age and older	Approved

\*Extra approvals not noted in August story. Source: [Go or no go? Novo awaits call on oral sema](#), August 30, 2019.

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