

EMD Serono pipeline

May 18, 2017

Phase I

M2698
p70S6K & Akt inhibitor
Solid tumors

M3814
DNA-PK inhibitor
Solid tumors

M9831 (VX-984)
DNA-PK inhibitor
Solid tumors

M6620 (VX-970)
ATR inhibitor
Solid tumors

M4344 (VX-803)
ATR inhibitor
Solid tumors

M7583
BTK inhibitor
Hematological malignancies

avelumab
anti-PD-L1 mAb
Solid tumors

avelumab
anti-PD-L1 mAb
Hematological malignancies

M9241 (NHS-IL12)⁸
Cancer immunotherapy
Solid tumors

M7824
anti-PD-L1/TGFbeta trap
Solid tumors

M1095 (ALX-0761)¹⁰
anti-IL-17 A/F nanobody
Psoriasis

Phase II

tepotinib
c-Met kinase inhibitor
Non-small cell lung cancer

tepotinib
c-Met kinase inhibitor
Hepatocellular cancer

avelumab anti-PD-L1 mAb
Merkel cell cancer 1L¹

sprifermin
fibroblast growth factor 18
Osteoarthritis

atacept
anti-Blys/anti-APRIL fusion protein
Systemic lupus erythematosus

atacept
anti-Blys/anti-APRIL fusion protein
IgA nephropathy

abrituzumab
anti-CD 51 mAb
Systemic sclerosis with interstitial lung dis.

evobrutinib
BTK inhibitor
Rheumatoid arthritis

evobrutinib
BTK inhibitor
Systemic lupus erythematosus

evobrutinib
BTK inhibitor
Multiple sclerosis

Phase III

avelumab - anti-PD-L1 mAb
Non-small cell lung cancer 1L¹

avelumab - anti-PD-L1 mAb
Non-small cell lung cancer 2L²

avelumab - anti-PD-L1 mAb
Gastric cancer 1L-M^{1M}

avelumab - anti-PD-L1 mAb
Gastric cancer 3L³

avelumab - anti-PD-L1 mAb
Ovarian cancer platinum resistant/refractory

avelumab - anti-PD-L1 mAb
Ovarian cancer 1L¹

avelumab - anti-PD-L1 mAb
Urothelial cancer 1L-M^{1M}

avelumab - anti-PD-L1 mAb
Renal cell cancer 1L¹

avelumab - anti-PD-L1 mAb
Locally advanced head and neck cancer

MSB 11022⁹
proposed biosimilar of adalimumab
Chronic plaque psoriasis

Registration

cladribine⁴ tablets
lymphocyte targeting agent
Relapsing-remitting multiple sclerosis

avelumab⁶ anti-PD-L1 mAb
Merkel cell cancer (EU)

Recently Registered

avelumab⁵ - anti-PD-L1 mAb
Merkel cell cancer (US)

avelumab⁷ - anti-PD-L1 mAb
Urothelial cancer (US)

- Neurology
- Oncology
- Immunology
- Immuno-Oncology
- Biosimilars

¹ First Line treatment; ^{1M} First Line maintenance treatment; ² Second Line treatment; ³ Third Line treatment;

⁴ As announced on July 18, 2016, the EMA has accepted for review the Marketing Authorization Application (MAA) of Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis.

⁵ As announced on March 23, 2017, the US FDA has granted accelerated approval of avelumab for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication was approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab has not yet been approved for metastatic MCC outside of the US.

⁶ As announced on October 31, 2016, the EMA has validated for review Merck KGaA, Darmstadt, Germany's MAA for avelumab, for the proposed indication of metastatic Merkel cell cancer.

⁷ As announced on May 9, 2017 the US FDA granted accelerated approval of avelumab for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy therapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication was approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab has not yet been approved for metastatic UC outside of the US.

⁸ Sponsored by the National Cancer Institute (USA).

⁹ On April 24, 2017 the divestment of Merck KGaA, Darmstadt, Germany's Biosimilars business to Fresenius was announced. Closing is expected in H2, 2017, subject to regulatory approvals and other conditions.

¹⁰ As announced on March 30, 2017 in an agreement with Avillion, anti-IL-17 A/F nanobody will be developed by Avillion for plaque psoriasis and commercialized by Merck KGaA, Darmstadt, Germany.

