Underlined items indicate changes from the previous announcement on Oct 31, 2018.

## Oncology (1/2)

*Compounds with "In-house" in this column include ones discovered by collaborative research.

| Generic Name<br>Code No.<br>(Brand Name) | Classification | Target Disease | Phase / Area | Dosage Form | Licensor* | Focus Area approach |
|---|---|---|---|---|---|---|
| **enzalutamide<br>MDV3100<br>(XTANDI®)** | Androgen receptor inhibitor | Non-metastatic hormone-sensitive prostate cancer | P-III / US, Europe, Asia | Oral | Pfizer | |
| | | Metastatic hormone-sensitive prostate cancer | P-III / US, Europe, Japan, Asia | | | |
| **gilteritinib<br>ASP2215<br>(XOSPATA®)** | FLT3 inhibitor | Relapsed or refractory acute myeloid leukemia | Approved (Nov. 2018) / US<br>P-III / Europe, Asia | Oral | In-house | |
| | | Post-chemo maintenance acute myeloid leukemia | P-III / US, Europe, Japan, Asia | | | |
| | | Post-HSCT maintenance acute myeloid leukemia | P-III / US, Europe, Japan, Asia | | | |
| | | Newly diagnosed acute myeloid leukemia<br>with low intensity induction of chemotherapy | P-III / US, Europe, Japan, Asia | | | |
| | | Newly diagnosed acute myeloid leukemia<br>with high intensity induction of chemotherapy | P-I / US, Japan | | | |
| **degarelix<br>ASP3550<br>(GONAX®)** | GnRH antagonist | Prostate cancer (12-week formulation) | Approved (Jan. 2019) / Japan | Injection | Ferring | |
| **zolbetuximab<br>IMAB362** | Anti-Claudin 18.2<br>monoclonal antibody | Gastric and gastroesophageal junction adenocarcinoma | P-III / US, Europe, Japan, Asia | Injection | In-house<br>(Ganymed) | |
| | | Pancreatic adenocarcinoma | P-II / US, Europe, Japan, Asia | | | |
| **enfortumab vedotin<br>ASG-22ME** | ADC targeting nectin-4 | Urothelial cancer | P-III / US, Europe, Japan, Asia | Injection | In-house<br>[Co-development with Seattle Genetics] | |
| **AGS-16C3F** | ADC targeting ENPP3 | Renal cell carcinoma | P-II / US, Europe | Injection | In-house<br>[ADC technology in-licensed from Seattle Genetics] | |
| **ASP1650** | Anti-Claudin 6<br>monoclonal antibody | Testicular cancer | P-II / US | Injection | In-house<br>(Ganymed) | |

## Oncology (2/2)

*Compounds with "In-house" in this column include ones discovered by collaborative research.

| Generic Name<br>Code No.<br>(Brand Name) | Classification | Target Disease | Phase / Area | Dosage Form | Licensor* | Focus Area approach |
|---|---|---|---|---|---|---|
| **ASP1235/AGS62P1** | | Acute myeloid leukemia | P-I | Injection | In-house<br>(ADC technology, EuCODE license from Ambrx) | |
| **ASP8374/PTZ-201** | | Cancer | P-I | Injection | In-house<br>(Potenza Therapeutics) | Biology:<br>Cancer Immunology |
| **ASP1948/PTZ-329** | | Cancer | P-I | Injection | In-house<br>(Potenza Therapeutics) | Biology:<br>Cancer Immunology |
| **ASP1951/PTZ-522** | | Cancer | P-I | Injection | In-house<br>(Potenza Therapeutics) | Biology:<br>Cancer Immunology |

**Updates from the previous announcement (Oct. 2018):**
**enzalutamide (MDV3100):** Removed the description of the approval in Europe for non-metastatic castration-resistant prostate cancer in Oct 2018.
**blinatumomab (AMG 103):** Removed the description of the approval in Japan for relapsed or refractory B-cell acute lymphoblastic leukemia in Sep 2018.
**degarelix(ASP3550):** 12-week formulation for prostate cancer approved in Japan in Jan 2019.
**gilteritinib (ASP2215):** Approved in US for FLT3 mutation positive relapsed or refractory acute myeloid leulemia in Nov 2018. Removed the description of approval in Japan for the same indication in Sep 2018.
**zolbetuximab (IMAB362):** Added a Phase 2 program for pancreatic adenocarcinoma.

## Immunology, Muscle disease and Ophthalmology

*Compounds with "In-house" in this column include ones discovered by collaborative research.

| Generic Name Code No. (Brand Name) | Classification | Target Disease | Phase / Area | Dosage Form | Licensor* | Focus Area approach |
|---|---|---|---|---|---|---|
| **peficitinib ASP015K** | JAK inhibitor | Rheumatoid arthritis | Filed (May 2018) / Japan | Oral | In-house | |
| **bleselumab ASKP1240** | Anti-CD40 monoclonal antibody | Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients | P-II / US | Injection | Kyowa Hakko Kirin | |
| **ASP5094** | Anti-α-9 integrin monoclonal antibody | Rheumatoid arthritis | P-II / Japan | Injection | In-house | |
| **reldesemtiv CK-2127107** | Fast skeletal muscle troponin activator | Spinal muscular atrophy | P-II / US | Oral | Cytokinetics | Biology: Molecular motor |
| | | Amyotrophic lateral sclerosis | P-II / US | | | |
| **ASP7317** | Cell therapy (Retinal pigment epithelium cell) | Dry age-related macular degeneration, Stargardt's disease | P-II / US | Injection | In-house (Astellas Institute for Regenerative Medicine) | Modality/Technology: Cell therapy |
| **ASP0367/MA-0211** | | Duchenne muscular dystrophy | P-I | Oral | In-house (Mitobridge) | Biology: Mitochondria |
| **ASP0892** | | Peanut allergy | P-I | Injection | Immunomic Therapeutics | Modality/Technology: LAMP-vax technology |

**Update from the previous announcement (Oct. 2018):**
**ASP4070/JRC2-LAMP-vax:** Discontinued the development of this program which was in Phase 2 for pollinosis caused by Japanese red cedar. Phase 2 study did not meet its primary endpoint.
**reldesemtiv(CK-2127107):** Discontinued the development for chronic obstructive pulmonary disease because Phase 2 study did not meet its primary endpoint.

## Urology and Nephrology

*Compounds with "In-house" in this column include ones discovered by collaborative research.

| Generic Name<br>Code No.<br>(Brand Name) | Classification | Target Disease | Phase / Area | Dosage Form | Licensor* | Focus Area Approach |
|---|---|---|---|---|---|---|
| **solifenacin**<br>**YM905** | Muscarine $M_3$ receptor antagonist | Neurogenic detrusor overactivity<br>in pediatric patients | Filed (Feb. 2017) / US | Oral | In-house | |
| **roxadustat**<br>**ASP1517/FG-4592** | HIF stabilizer | Anemia associated with chronic kidney disease<br>in patients on dialysis | Filed (Sep. 2018) / Japan<br>P-III / Europe | Oral | FibroGen | |
| | | Anemia associated with chronic kidney disease<br>in patients not on dialysis | P-III / Europe<br>P-III / Japan | | | |
| **mirabegron**<br>**YM178** | β3 receptor agonist | Neurogenic detrusor overactivity<br>in pediatric patients | P-III / Europe | Oral | In-house | |
| **ASP6294** | Nerve Growth Factor (NGF)<br>neutralization antibody | Bladder pain syndrome / Interstitial cystitis | P-II / Europe | Injection | In-house | |
| **ASP8302** | Muscarine $M_3$ receptor<br>positive allosteric modulator | Underactive bladder | P-II / Europe, Japan | Oral | In-house | |
| **ASP1128/MA-0217** | PPARδ modulator | Acute kidney injury | P-II / US | Injection | In-house<br>(Mitobridge) | Biology: Mitochondria |

**Update from the previous announcement (Oct. 2018):**
**ASP7713:** Discontinued Phase 1 program for underactive bladder.
**ASP1128/MA-0217:** Progressed from Phase 1 to Phase 2.

## Others

*Compounds with "In-house" in this column include ones discovered by collaborative research.

| Generic Name<br>Code No.<br>(Brand Name) | Classification | Target Disease | Phase / Area | Dosage Form | Licensor* | Focus Area approach |
|---|---|---|---|---|---|---|
| **ipragliflozin<br>ASP1941<br>(Suglat®)** | SGLT2 inhibitor | Type 1 diabetes | Approved (Dec. 2018) / Japan | Oral | In-house<br>[Co-development with Kotobuki] | |
| **romosozumab<br>AMG 785<br>(EVENITY®)** | Anti-Sclerostin monoclonal antibody | Osteoporosis in patinets at high risk of fracture | Approved (Jan. 2019) / Japan | Injection | Amgen<br>[Co-development with Amgen Astellas] | |
| **evolocumab<br>AMG 145<br>(Repatha®)** | Anti-PCSK-9 monoclonal antibody | Statin intolerant hypercholesterolemia | Filed (Aug. 2018) / Japan | Injection | Amgen<br>[Co-development with Amgen Astellas] | |
| **fidaxomicin** | Macrocyclic antibiotic | *Clostridium difficile* infection in pediatric patients | P-III / Europe | Oral | Merck | |
| **fezolinetant<br>ESN364** | NK3 receptor antagonist | Menopause-related vasomotor symptoms | P-II / US<br>P-I / Japan | Oral | In-house<br>(Ogeda) | |
| **ASP0819** | $Ca^{2+}$ activated $K^{+}$ channel opener | Fibromyalgia | P-II / US | Oral | In-house | |
| **ASP4345** | Dopamine $D_1$ receptor positive allosteric modulator | Cognitive impairment associated with schizophrenia | P-II / US | Oral | In-house | |
| **isavuconazole<br>ASP9766** | Azole antifungal | Invasive aspergillosis and mucormycosis in pediatric patients | P-II / US | Injection | Basilea | |
| **MucoRice-CTB** | | Prophylaxis of diarrhea caused by *Vibrio cholerae* | P-I | Oral | The Institute of Medical Science, the University of Tokyo | |
| **ASP3772** | | Prevention of pneumococcal disease | P-I | Injection | Affinivax | |

**Updates from the previous announcement (Oct. 2018):**
**linaclotide (ASP0456):** Removed the description of the approval in Japan for chronic constipation in Aug 2018.
**romosozumab (AMG 785):** Approved in Japan for osteoporosis in patients at high risk of fracture in Jan 2019.
**ipragliflozin (ASP1941):** Approved in Japan for type 1 diabetes in Dec 2018.
**ASP1807/CC8464:** Discontinued the development of this program which was in Phase 1 for neuropathic pain.
**ASP3772:** Progressed to Phase 1 for prevention of pneumococcal disease.