

Oncology

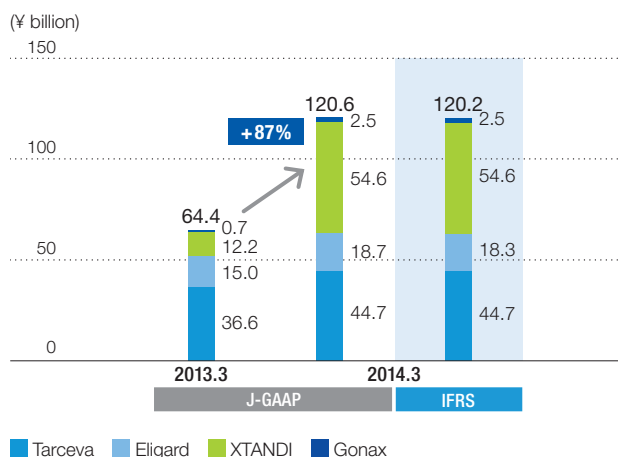
New drug XTANDI is driving strong growth in our oncology franchise toward GCL status.

Astellas is focusing on establishing a Global Category Leader (GCL) position in the field of oncology after urology and transplantation.

Our current oncology product lineup consists of XTANDI, Eligard and Gonax (all prostate cancer treatments) and Tarceva (for treatment of non-small cell lung cancer and pancreatic cancer). Aggregate sales of these four products saw sales in the oncology field soar 87% year on year in fiscal 2013 to ¥120.6 billion.

XTANDI is a significant growth driver for us in the oncology field. It grew significantly with the U.S. net sales of US\$441 million in fiscal 2013, an increase of 201% in year-on-year terms. XTANDI was launched in the U.K. in July 2013 and later in other EMEA markets. Net sales in EMEA in fiscal 2013 totaled €71 million. In Japan, we launched XTANDI in May 2014 after gaining regulatory approval in March. The product is currently available in over 25 countries around the world. With the aim of maximizing the value of XTANDI, we have filed applications in Europe and the U.S. for its approval for prostate cancer in chemotherapy-naïve patients. Clinical trials in earlier stage prostate cancer and breast cancer patients are also ongoing.

Total Sales of XTANDI, Tarceva, Eligard and Gonax



In fiscal 2013, Tarceva-related revenues grew steadily, increasing 1.4% year on year on a U.S. dollar basis to US\$446 million. In the U.S., Astellas is co-promoting Tarceva with Genentech, Inc., with earnings split equally. In regions outside the U.S., Astellas has a license agreement with F. Hoffmann-La Roche Ltd and receives royalties based on sales.

Eligard is currently marketed in EMEA, Asia & Oceania. Net sales in EMEA in fiscal 2013 declined 0.5% to €139 million. Sales of Gonax, which was launched in Japan in October 2012, was ¥2.5 billion in fiscal 2013.

As for new drug candidates, clinical trials are also ongoing for more than ten projects in the oncology field at present.

Oncology Pipeline

(as of August 1, 2014)

	Project	Phase 1	Phase 2	Phase 3	Filed
Small molecule	Enzalutamide (XTANDI)	Prostate cancer: pre-chemo, EU/US/JP/Asia (Filed in EU/US)			
		Non-metastatic castration-resistant prostate cancer: EU/US/Asia			
		Breast cancer: EU/US			
	Erlotinib (Tarceva)	Pediatric ependymoma: US			
	Degarelix (Gonax)	Prostate cancer: Japan (3-month formulation)			
	ASP1707	Prostate cancer			
	ASP2215	Acute Myeloid Leukemia			
	ASP5878	Cancer			
	AMG 337	Gastric cancer: Japan			
	ASP8273	Non-small cell lung cancer			
Antibody	Pilotumumab AMG 102	Gastric cancer: Japan			
	AGS-16M8F/ AGS-16C3F	Renal cancer			
	ASG-22ME	Solid tumors			
	ASG-15ME	Bladder cancer			
	AGS67E	Lymphoid malignancy			