



Consulting on Advanced Biologicals

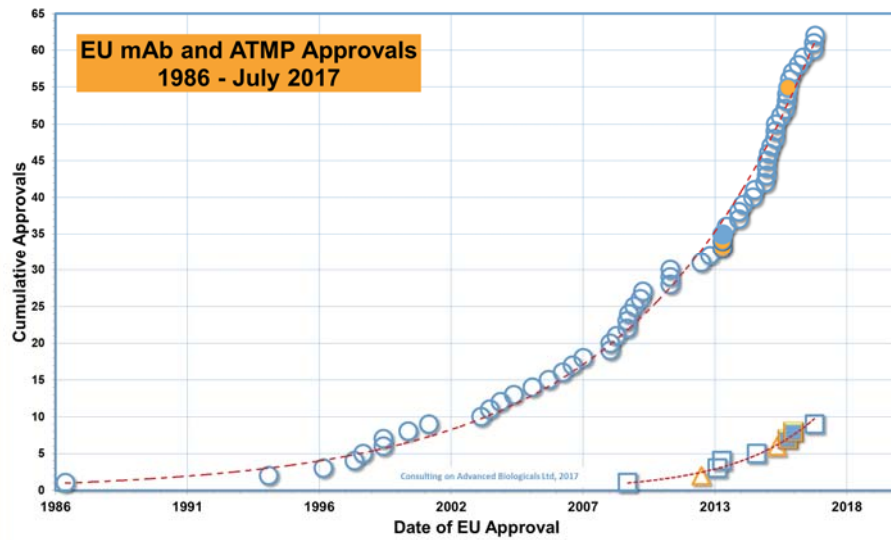
Chair Intro

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ADOPTION OF NEW TECHNOLOGY TAKES TIME

Monoclonal antibodies invented c.1975



FDA Approvals

Product	INN/Description	Type	Indication/s	Company	Type	Approved
Provenge	Sipuleucel-T	Immunotherapy	asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.	Dendreon Corporation	BLA	Apr 10
LaViv	Azficel-T	Skin rejuvenation	For the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults.	Fibrocell Technologies, Inc.	BLA	Jun 11
XXXXXXXXXX	Hematopoietic Progenitor Cells Cord	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation	New York Blood Center	BLA	May 14
Gintuit	Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen	Engineered Skin	treatment of mucogingival conditions in adults	Organogenesis	BLA	Mar 12
XXXXXXXXXX	Hematopoietic Progenitor Cells Cord	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation	Stem Cell Therapy	BLA	May 14
HPC, Cord Blood	Hematopoietic Progenitor Cells, Cord	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation	Stem Cell Therapy	BLA	May 14
XXXXXXXXXX	Hematopoietic Progenitor Cells Cord	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation	SSM Cardinal Medical Center	BLA	May 14
XXXXXXXXXX	HPC, Cord Blood	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation	LifeSouth Centers, Inc	BLA	Jun 13
Imlygic	talimogene laherparepvec	Oncolytic virus (gene therapy)			BLA	
XXXXXXXXXX	HPC, Cord Blood	Cell Blood	unrelated donor hematopoietic progenitor cell transplantation procedures	Stem Cell Therapy	BLA	May 14
MACI	Autologous Cultured Chondrocytes on a Porcine Collagen Membrane	Chondrocyte	repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults.	Vericel Corporation	BLA	Dec 16

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MORE ON THE WAY?

😊FDA and 😊EMA SUBMISSIONS in 2017

- ▶ 😊 Tigenix (ongoing since 2015)
 - ▶ Cx601 (eASC)
 - ▶ Anal fistulas, Crohn's disease
- ▶ 😊 Kiadis
 - ▶ ATIR
 - ▶ Haploidentical donor lymphocytes depleted of alloreactive T cells
 - ▶ for the treatment of prevention (reduction) of transplantrelated mortality (caused by graft-versushost disease and/or infections) following haploidentical allogeneic hematopoietic stem cell
- ▶ 😊 😊 Spark Therapeutics
 - ▶ voretigene neparvovec (LUXTURNA™)
 - ▶ AAV2-hRPE65v2
 - ▶ vision loss due to Leber congenital amaurosis or retinitis pigmentosa caused by confirmed biallelic RPE65 mutations.

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MORE ON THE WAY?

😊FDA and 😊EMA SUBMISSIONS in 2017

- ▶ 😊 Novartis
 - ▶ tisagenlecleucel-T (CTL019)
 - ▶ relapsed and refractory (r/r) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL)
- ▶ 😊 😊 Kite Pharma
 - ▶ axicabtagene ciloleucel (KTE-C19)
 - ▶ retroviral vector
 - ▶ relapsed or refractory DLBCL, PMBCL and TFL

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