2016 Medicines in Development for Osteoporosis

Drug Name	Sponsor	Indication	Development Phase
abaloparatide (synthetic peptide analog of human parathyroid hormone-related protein)	Radius Health *Waltham, MA*	postmenopausal osteoporosis (subcutaneous injection)	Phase III www.radiuspharm.com
		postmenopausal osteoporosis (transdermal patch)	Phase II completed www.radiuspharm.com
blosozumab (SOST protein inhibitor)	Eli Lilly *Indianapolis, IN*	postmenopausal osteoporosis	Phase I www.lilly.com
DS-1501 (anti-siglec-15 antibody)	Daiichi Sankyo *Parsippany, NJ*	osteoporosis	Phase I www.dsi.com
odanacatib (cathepsin K inhibitor)	Merck *Kenilworth, NJ*	male osteoporosis, postmenopausal osteoporosis	Phase III www.merck.com
		corticosteroid-induced osteoporosis	Phase I www.merck.com
Prolia® denosumab	Amgen *Thousand Oaks, CA*	corticosteroid-induced osteoporosis	Phase III www.amgen.com
romosozumab (SOST protein inhibitor)	Amgen *Thousand Oaks, CA* UCB *Smyrna, GA*	male osteoporosis, postmenopausal osteoporosis	Phase III www.amgen.com www.ucb-usa.com

Drug Name	Sponsor	Indication	Development Phase
TBRIA™ calcitonin-salmon [rDNA origin] delayed release tablets	Tarsa Therapeutics *Philadelphia, PA*	postmenopausal osteoporosis	application submitted www.tarsatherapeutics.com
		postmenopausal osteoporosis (prevention)	Phase II completed www.tarsatherapeutics.com
teriparatide transdermal-hPTH(1-34) (parathyroid hormone receptor type 1 agonist)	Corium International *Menlo Park, CA*	osteoporosis	Phase II www.coriumgroup.com
Weekly ZP-PTH (teriparatide transdermal patch)	Zosano Pharma *Fremont, CA*	severe osteoporosis	Phase I completed www.zosanopharma.com

The content of this report has been obtained through public, government and industry sources, and the Springer "Adis Insight" database based on the latest information. **Report current as of February 4, 2016.** The medicines in this listing include medicines being developed by U.S.-based companies conducting trials in the United States and abroad, PhRMA-member companies conducting trials in the United States and abroad, and foreign companies conducting clinical trials in the United States. Some products may not be in active clinical trials. The information may not be comprehensive. For more, specific information about a particular product, contact the individual company directly or go to www.clinicaltrials.gov. The entire series of *Medicines in Development* is available on PhRMA's website, www.phrma.org.

Definitions

Application Submitted—An application for marketing has been submitted by the company to the U.S. Food and Drug Administration (FDA).

Phase I—Researchers test the investigational drug or biologic in a small group of people, usually between 20 and 100 healthy adult volunteers, to evaluate its initial safety and tolerability profile, determine a safe dosage range, and identify potential side effects.

Phase II—The investigational drug or biologic is given to volunteer patients, usually between 100 and 500, to determine whether it is effective, identify an optimal dose, and to further evaluate its short-term safety.

Phase III—The investigational drug or biologic is given to a larger, more diverse patient population, often involving between 1,000 and 5,000 patients (but sometimes many more), to generate statistically significant evidence to confirm its safety and effectiveness. Phase III studies are the longest studies and usually take place in multiple sites around the world.