

# Takeda R&D: Translating Science into Highly Innovative, Life-Changing Medicines

Takeda is an R&D driven, global biopharmaceutical leader. For over 200 years, we've focused on bringing better health and a brighter future to people around the world by translating science into life-changing medicines that make a critical difference for patients. We have earned our place among the top 10 global innovators and we are confident in our ability to execute on our near-term and sustained growth opportunities through 2025 and beyond.

Takeda supports dedicated R&D efforts across three areas: Innovative Biopharma, Plasma Derived Therapies (PDT) and Vaccines. We have a diverse portfolio of approved medicines and we are committed to innovative expansions of our 14 global growth brands as we believe they could deliver significant benefit to new patients.

The R&D engine for Innovative Biopharma, the largest component of our R&D investment, has produced exciting new molecular entities (NMEs) that represent potential best-in-class and/or first-in-class medicines in areas of high unmet medical need across our core Therapeutic Areas: Oncology, Rare Diseases, Neuroscience and Gastroenterology. Over the past several years, and more recently bolstered by our acquisition of Shire, we have increased our focus on more targeted patient populations where there is the potential for greater therapeutic benefit, smaller and less costly development programs, and faster tracks to registration with enhanced patent protection and marketing rights.

Over the next several years, our pipeline is projected to deliver value in two distinct waves.

## 1 WAVE 1: NEAR-TERM GROWTH GLOBAL BRAND EXPANSION AND 12 NMEs WITH THE POTENTIAL FOR 14 LAUNCHES THROUGH FY2024

### 14 GLOBAL GROWTH BRANDS

Our 14 global growth brands continue to generate significant opportunities through new indications and geographic expansion. **With over 30 ongoing pivotal studies and 16 applications under review by regulatory agencies, we anticipate our global growth brands to generate at least 20 additional launches over the next 5 years.** We also intend to deliver at least 15 transformative medicines to patients in China by 2025.<sup>1</sup> Our 14 global growth brands will sustain us for the next 5 years through geographic expansion and additional indications.

For our 14 global growth brands, we are targeting the following extensions through FY24:

FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
<b>ENTYVIO:</b> <ul style="list-style-type: none"> <li>sc UC (US)<sup>2</sup></li> <li>CD (JP)</li> </ul> <b>NINLARO:</b> <ul style="list-style-type: none"> <li>NDMM SCT (JP)</li> </ul> <b>GATTEX:</b> <ul style="list-style-type: none"> <li>Pediatric (US)</li> </ul>	<b>ENTYVIO:</b> <ul style="list-style-type: none"> <li>UC &amp; CD (CN)</li> <li>sc CD &amp; UC (US, EU)</li> </ul> <b>NINLARO:</b> <ul style="list-style-type: none"> <li>NDMM nSCT (US, EU)</li> </ul> <b>ALUNBRIG:</b> <ul style="list-style-type: none"> <li>1L NSCLC (US, EU)</li> <li>2L NSCLC (JP)</li> </ul> <b>GATTEX:</b> <ul style="list-style-type: none"> <li>SBS (JP)</li> </ul> <b>TAKHZYRO:</b> <ul style="list-style-type: none"> <li>HAE (CN)</li> </ul> <b>VIPRIV:</b> <ul style="list-style-type: none"> <li>Gaucher Disease (CN)</li> </ul>	<b>TAKHZYRO:</b> <ul style="list-style-type: none"> <li>HAE (JP)</li> </ul> <b>NINLARO:</b> <ul style="list-style-type: none"> <li>NDMM (US, EU, JP)</li> <li>NDMM nSCT (JP)</li> </ul> <b>ALUNBRIG:</b> <ul style="list-style-type: none"> <li>1L &amp; 2L NSCLC (CN)</li> <li>H2H alectinib (EU)</li> <li>Post-2Gen (US, EU)</li> </ul> <b>ALOFISEL:</b> <ul style="list-style-type: none"> <li>CPF (JP)</li> </ul>	<b>NINLARO:</b> <ul style="list-style-type: none"> <li>NDMM SCT (US, EU)</li> </ul> <b>GATTEX:</b> <ul style="list-style-type: none"> <li>SBS (CN)</li> </ul> <b>ALUNBRIG:</b> <ul style="list-style-type: none"> <li>H2H alectinib (US)</li> </ul> <b>ENTYVIO:</b> <ul style="list-style-type: none"> <li>GvHD (EU)</li> </ul>	<b>ALOFISEL:</b> <ul style="list-style-type: none"> <li>CPF (US)</li> <li>CCF</li> </ul>	<b>TAKHZYRO:</b> <ul style="list-style-type: none"> <li>BMA (US)</li> </ul> <b>NINLARO:</b> <ul style="list-style-type: none"> <li>NDMM nSCT (CN)</li> </ul>

### 12 NMEs WITH THE POTENTIAL FOR 14 BEST-IN-CLASS/FIRST-IN-CLASS LAUNCHES

The main driver for new product launches in the near term are our unique NMEs which represent several potential best-in-class / first-in-class therapies. Of these programs, 8 are in pivotal studies and we intend to have data read outs in the next 3-5 years. These anticipated product launches are intended to fuel our growth trajectory while our next-generation platforms mature.

TARGET LAUNCH	FY2020	FY2021	—	FY2023	FY2024
	TAK-721, EoE	TAK-788, 2L NSCLC TAK-924, HR-MDS TAK-620, CMV infection in transplant TAK-003, Dengue Vaccine TAK-609, Hunter CNS (IT)		TAK-007, Hematologic Malignancies TAK-611, MLD TAK-788, 1L NSCLC TAK-755, cTTP TAK-935, DEE	TAK-924, AML TAK-607, Complications of prematurity Orexin2R-ag, Narcolepsy T1

1 Of the >15 new medicines, 6 represent our global brands: Entyvio®, Alunbrig®, Ninlaro®, Vpriv®, Takhzyro®, Adynovate®  
 2 Takeda received a complete response letter from the U.S. FDA and is working closely with the agency on a path to approval.









# WAVE 2: SUSTAINED GROWTH (FY2025 AND BEYOND)

## >20 PROGRAMS AND NEXT GENERATION PLATFORMS

Our research engine, comprised of our internal research capabilities and external partnerships, is quickly advancing a steady stream of next generation therapies designed to provide **transformative or curative potential** for targeted populations with high unmet need, in our core Therapeutic Areas. These programs are based on targets with strong human validation, represent diverse modalities and leverage new platform capabilities in cell therapy, gene therapy and data sciences. *Programs with strong efficacy data may enable accelerated development and accelerated regulatory pathways.*

	PROGRAMS	NEXT-GENERATION PLATFORMS
<b>ONCOLOGY</b> 	<ul style="list-style-type: none"> <li>• TAK-164 (GI Malignancies)</li> <li>• TAK-252 (Solid tumors)</li> <li>• TAK-573 (R/R MM)</li> <li>• TAK-981 (Multiple cancers)</li> </ul>	<ul style="list-style-type: none"> <li>• Cell Therapies and Immune Engagers</li> <li>• Targeted Innate Immune Modulation</li> <li>• Next-gen Checkpoint Modulators</li> </ul>
<b>RARE DISEASES (IHM)</b> 	<ul style="list-style-type: none"> <li>• TAK-754 (HemA)</li> <li>• TAK-079 (MG, ITP)</li> <li>• TAK-755 (iTTP, SCD)</li> </ul>	<ul style="list-style-type: none"> <li>• Gene Therapy</li> </ul>
<b>NEUROSCIENCE</b> 	<ul style="list-style-type: none"> <li>• TAK-341 (Parkinson's disease)</li> <li>• Orexin 2R-ag (Sleep disorders)</li> <li>• TAK-418 (Kabuki Syndrome)</li> <li>• WVE-120101/102 (Huntington's disease)</li> <li>• TAK-935 (CRPS)</li> <li>• Psychiatry Assets (TAK-041 CIAS NS, TAK-831 CIAS NS, TAK-653 TRD)</li> </ul>	<ul style="list-style-type: none"> <li>• Gene Therapy</li> <li>• Other platforms including. RNA Modulation, Antibody Transport Vehicle</li> </ul>
<b>GASTROENTEROLOGY</b> 	<ul style="list-style-type: none"> <li>• KUMA-062 (Celiac disease)</li> <li>• TAK-101 (Celiac disease)</li> <li>• TAK-018 (Crohn's disease, post -op and ileitis)</li> <li>• TAK-671 (Acute pancreatitis)</li> <li>• TAK-906 (Gastroparesis)</li> <li>• TAK-951 (Nausea &amp; vomiting - all cause)</li> <li>• TAK-954 (POGD)</li> </ul>	<ul style="list-style-type: none"> <li>• Gene Therapy</li> <li>• Microbiome</li> <li>• Cell Therapy</li> </ul>



More than 4,500 employees across Takeda R&D are advancing our near-term catalysts with a sense of urgency while building our next-generation platforms to sustain our long-term growth so that we may fulfill our mission to deliver better health and brighter futures to even more patients around the world.

## GLOSSARY OF ABBREVIATIONS

<b>1L</b>	first line
<b>2L</b>	second line
<b>AML</b>	acute myeloid leukemia
<b>BMA</b>	bradykinin mediated angioedema
<b>CCF</b>	complex cryptoglandular fistula
<b>CD</b>	Crohn's disease
<b>CIAS</b>	cognitive impairment associated with schizophrenia
<b>CMV</b>	cytomegalovirus
<b>CN</b>	China
<b>CNS</b>	central nervous system
<b>CPF</b>	complex perianal fistula
<b>CRPS</b>	complex regional pain syndrome
<b>cTTP</b>	congenital thrombotic thrombocytopenic purpura
<b>DEE</b>	developmental and epileptic encephalopathies
<b>EOE</b>	eosinophilic esophagitis
<b>EU</b>	European Union
<b>GI</b>	gastrointestinal
<b>GvHD</b>	graft versus host disease
<b>HAE</b>	hereditary angioedema
<b>H2H</b>	head to head
<b>HemA</b>	hemophilia A
<b>HR MDS</b>	high-risk myelodysplastic syndromes
<b>IHM</b>	immunology hematology metabolic
<b>IT</b>	intrathecal
<b>ITP</b>	idiopathic thrombocytopenic purpura
<b>iTTP</b>	immune thrombotic thrombocytopenic purpura

<b>JP</b>	Japan
<b>MG</b>	myasthenia gravis
<b>MLD</b>	metachromatic leukodystrophy
<b>NDMM</b>	newly diagnosed multiple myeloma
<b>NME</b>	new molecular entity
<b>NSCLC</b>	non-small cell lung cancer
<b>nSCT</b>	non stem cell transplant
<b>NS</b>	negative symptoms
<b>Orexin2R-ag</b>	orexin 2 receptor agonist
<b>PDT</b>	Plasma Derived Therapies (business unit)
<b>Ped</b>	pediatric
<b>POC</b>	proof of concept
<b>Post-2 gen</b>	after 2nd generation ALK inhibitor
<b>Post-op</b>	post-operative
<b>POGD</b>	post-operative gastrointestinal dysfunction
<b>R&amp;D</b>	research and development
<b>RNA</b>	ribonucleic acid
<b>R/R MM</b>	relapse/refractory multiple myeloma
<b>SBS</b>	short bowel syndrome
<b>sc</b>	subcutaneous formulation
<b>SCD</b>	sickle cell disease
<b>SCT</b>	stem cell transplant
<b>T1</b>	type 1
<b>TRD</b>	treatment resistant depression
<b>UC</b>	ulcerative colitis
<b>US</b>	United States

# IMPORTANT NOTE

## Forward-Looking Statements

This document is being circulated in connection with Takeda's R&D Day held on November 14, 2019. Any materials distributed in connection with this document may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could", "anticipates", "estimates", "projects" or similar expressions or the negative thereof. Forward-looking statements in this document are based on Takeda's estimates and assumptions only as of the date hereof. Such forward-looking statements do not represent any guarantee by Takeda or its management of future performance and involve known and unknown risks, uncertainties and other factors. For more information on risks and/or other factors which may affect Takeda's results, performance, achievements, or financial position, see "Item 3. Key Information—D. Risk Factors" in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: <https://www.takeda.com/investors/reports/sec-filings/> or at [www.sec.gov](http://www.sec.gov). Future results, performance, achievements or financial position of Takeda could differ materially from those expressed in or implied by the forward-looking statements. Persons receiving this document should not rely unduly on any forward-looking statements. Takeda undertakes no obligation to update any of the forward-looking statements contained in this document or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results of Takeda in this document may not be indicative of, and are not an estimate, forecast or projection of Takeda's future results.

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