Roche: Commercial Opportunities

Teresa Graham | Head of Global Product Strategy

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Strong short term news flow
Diversifying the late stage pipeline and setting new standards of care

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Filing Date</th>
<th>Market Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>risdiplam</td>
<td>SMA</td>
<td>2019 in type 1/2/3</td>
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<tr>
<td>satralizumab</td>
<td>NMOSD</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>HTT-ASO</td>
<td>Huntington’s</td>
<td>Ph II &amp; III ongoing; filing latest 2022</td>
<td></td>
</tr>
<tr>
<td>Gazyva</td>
<td>Lupus Nephritis</td>
<td>initiating Ph III</td>
<td></td>
</tr>
<tr>
<td>etrolizumab</td>
<td>UC/Crohn’s Disease</td>
<td>filing in UC in 2020</td>
<td></td>
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<tr>
<td>PDS</td>
<td>nAMD</td>
<td>fully recruited; filing in 2020</td>
<td></td>
</tr>
<tr>
<td>faricimab</td>
<td>nAMD/DME</td>
<td>recruitment ahead of plan; filing in 2021/22</td>
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</tr>
</tbody>
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<th>Product</th>
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<tr>
<td>Tecentriq</td>
<td>1L HCC</td>
<td>2019/20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adj. MIBC</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FL Ovarian Cancer</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1L BRAFm Melanoma</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1L mUC</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Neoadj. TNBC</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Neoadj NSCLC</td>
<td>2021</td>
<td></td>
</tr>
<tr>
<td>ipatasertib</td>
<td>1L/2L TNBC</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1L+ HR+ BC (chemo treated only)</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1L mCRPC</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>idasanutlin</td>
<td>R/R AML</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>H+P FDC-SC</td>
<td>eBC, 1L HER2+ BC</td>
<td>2019/20</td>
<td></td>
</tr>
<tr>
<td>Polivy</td>
<td>1L DLBCL</td>
<td>2020/21</td>
<td></td>
</tr>
</tbody>
</table>

Source: Roche/Genentech, incidence/prevalence in the major markets (US, FR, IT, ES, GB); 1 including China; SOC=standard of care; SMA=spinal muscular atrophy; NMOSD=neuromyelitis optica spectrum disorder; UC=ulcerative colitis; CD=Crohn’s disease; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; HCC=hepatocellular carcinoma; TNBC=triple-negative breast cancer; FL=front line; R/R AML=relapsed/refractory acute myeloid leukemia; FDC=fixed dose combination; HR=hormone receptor; mCRPC=metastatic castration resistant prostate cancer; DLBCL=diffuse large B-cell lymphoma; NSCLC=non-small cell lung cancer; AC=all comers
Late stage pipeline

**ONCOLOGY / HEMATOLOGY**
- Breast, Gyn
  - HER2+ BC
  - TNBC
  - HR+ BC
  - OC
- Lung, Skin, Rare
  - NSCLC
  - SCLC
  - ALK+ NSCLC
  - ROS1+ NSCLC
  - NTRK+ pan tumor
  - SCCHN
  - Melanoma
- GI/GU
  - RCC
  - UC
  - CRPC
  - HCC
- Hematology
  - CLL
  - DLBCL
  - iNHL
  - AML
  - MM
  - Hemophilia A

**IMMUNOLOGY**
- Ulcerative colitis
- Crohn's disease
- Nasal polyps
- Lupus Nephritis

**OPHTHALMOLOGY**
- nAMD
- DME

**NEUROSCIENCE**
- SMA
- DMD
- Huntington's
- Autism
- Alzheimer's
- NMOSD

**INFECTIOUS DISEASES**
- Influenza A/B
Oncology/Hematology portfolio

ONCOLOGY / HEMATOLOGY
- Breast, Gyn:
  - HER2+ BC
  - TNBC
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INFECTIONOUS DISEASES
- Influenza A/B

NEUROSCIENCE
- SMA
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- Huntington’s
- Autism
- Alzheimer’s
- NMOSD
Expanding oncology franchise into new tumor types

**Hematology**
- DLBCL
- iNHL
- CLL

**Lung, Skin, Rare Tumors**
- NSCLC
- BRAFm Melanoma

**Breast/Gyn**
- HER2+ BC
- OC

**GI/GU**
- CRC
- UC

**2018**
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔

**2020**
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔

- CD20 x CD3 bispecifics
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔
- ✔

**Expanding oncology franchise into new tumor types**

CLL = Chronic lymphoid leukemia; DLBCL = Diffuse large B-cell lymphoma; iNHL = Indolent Non-Hodgkin's lymphoma; AML = Acute myeloid leukemia; MM = Multiple myeloma; NSCLC = Non-Small Cell Lung Cancer; SCLC = Small Cell Lung Cancer; SCCHN = Head & Neck Squamous Cell Carcinoma; TNBC = Triple Negative Breast Cancer; OC = Ovarian Cancer; UC = Urothelial Carcinoma; HCC = Hepatocellular Carcinoma; RCC = Renal Cell Carcinoma; CRPC = Castration Resistant Prostate Cancer; CRC = Colorectal Cancer; Nenclesta in collaboration with AbbVie
Advancing medicines into early disease  
Curative potential for the largest number of patients

<table>
<thead>
<tr>
<th>Breast / Gyn</th>
<th>Lung, Skin, Rare</th>
<th>GI / GU</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;80% of TNBC pts treated in the adjuvant setting</td>
<td>25-35% of NSCLC patients have resectable disease</td>
<td>&gt;2.5x more patients with early UC than metastatic UC</td>
</tr>
<tr>
<td>IMpassion030: Adj. TNBC</td>
<td>IMpower030: Neoadj. NSCLC</td>
<td>IMvigor010: Adj. MIBC</td>
</tr>
<tr>
<td>IMpassion031: Neoadj. TNBC</td>
<td>IMpower010: Adj. NSCLC</td>
<td>ALBAN: NMIBC</td>
</tr>
<tr>
<td>GEPARDOUZE: Neoadj/adj. TNBC</td>
<td>IMvoke010: Adj. SCCHN</td>
<td>IMmotion010: Adj. RCC</td>
</tr>
<tr>
<td>IMpassion050: Neoadj. HER2+ BC</td>
<td>✔ NEOSPHERE: Neoadj. HER2+ BC</td>
<td>✔ ALINA: Adj. ALK+ NSCLC</td>
</tr>
<tr>
<td>✔ NEOSPHERE: Neoadj. HER2+ BC</td>
<td>✔ APHINITY: Adj. HER2+ BC</td>
<td>✔ KATHERINE: Adj. HER2+ BC</td>
</tr>
<tr>
<td>✔ KATHERINE: Adj. HER2+ BC</td>
<td>KAITLIN: Adj. HER2+ BC</td>
<td>KAITLIN: Adj. HER2+ BC</td>
</tr>
<tr>
<td>✔ KATHERINE: Adj. HER2+ BC</td>
<td>✔ KAITLIN: Adj. HER2+ BC</td>
<td>✔ KAITLIN: Adj. HER2+ BC</td>
</tr>
<tr>
<td>✔ KATHERINE: Adj. HER2+ BC</td>
<td>✔ KAITLIN: Adj. HER2+ BC</td>
<td>✔ KAITLIN: Adj. HER2+ BC</td>
</tr>
</tbody>
</table>

Source: Roche US/EU5 epidemiology; TNBC=triple negative breast cancer; NSCLC=non-small cell lung cancer; MIBC=muscle invasive bladder cancer; NMIBC=non-muscle invasive bladder cancer; RCC=renal cell carcinoma
**HER2+ breast cancer**

*Perjeta and Kadcyla forecasted to offset biosimilar erosion of Herceptin*

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**Consensus sales estimates: HER2+ franchise**

Herceptin decline offset by Perjeta and Kadcyla

<table>
<thead>
<tr>
<th>Year</th>
<th>Herceptin</th>
<th>Perjeta</th>
<th>Kadcyla</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019E</td>
<td></td>
<td></td>
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<tr>
<td>2020E</td>
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<tr>
<td>2021E</td>
<td></td>
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<tr>
<td>2022E</td>
<td></td>
<td></td>
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**Current standard of care in eBC**

- **APHINITY** uptake in adjuvant fuels Perjeta growth
- **KATHERINE** launch driving Kadcyla growth in patients with residual disease

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1. Source: Evaluate Pharma; 2. Epidemiology EU5 & US; 3. Adapted based on St Gallen Breast Cancer Conference 2019; eBC=Early Breast Cancer
Herceptin + Perjeta Subcutaneous Fixed Dose Combination
Reduced administration time, SC route strongly preferred by patients

- Positive Ph III (FeDeriCa) results show H+P FDC SC achieves equivalent serum concentrations as IV at cycle 7 in neoadjuvant HER2+ eBC
- SC formulations result in reduced drug delivery related healthcare costs and resource use
- US/EU filing in 2019/20

<table>
<thead>
<tr>
<th>Treatment option</th>
<th>Administration and observation schedule*</th>
<th>Total time</th>
</tr>
</thead>
<tbody>
<tr>
<td>H IV P IV</td>
<td>0.5 - 1.5 hours 1h 1h 2 - 6 h</td>
<td>~2.5-7.5 hours</td>
</tr>
<tr>
<td>H SC P IV</td>
<td>2 - 5 min 1h 1h 2 - 6 h</td>
<td>~2-6 hours</td>
</tr>
<tr>
<td>PH FDC SC</td>
<td>5 - 8 min 15 - 30 min Ranges driven by differences in loading and maintenance dose</td>
<td>~20-38 min</td>
</tr>
</tbody>
</table>

H+P=Herceptin+Perjeta; FDC=fixed dose combination; SC=subcutaneous; IV=intravenous; *Ranges driven by differences in loading and maintenance dose; H+P FDC SC in collaboration with Halozyme
Lung cancer

**Broad coverage with differentiated growth opportunities**

**Executing on launches in 1L lung cancer**

- **Tecentriq**: Strong launch in 1L SCLC; gaining traction in 1L NSCLC subgroups
- **Alecensa**: Continued uptake in 1L ALK+ with >70% new pt share in US
- **Rozlytrek**: Launch ongoing in ROS1+, NSCLC, NTRK+ (tumor agnostic)

**Lung cancer market growing to USD 33bn by 2024**

25-35% of patients have resectable disease\(^2\)

- 380k NSCLC incidence
- 120k Non-Metastatic
- 260k mNSCLC incidence

**Further growth potential in early NSCLC**

Three pivotal trials ongoing in early NSCLC
- **IMpower030**: Neoadj. NSCLC
- **IMpower010**: Adjuvant NSCLC
- **ALINA**: Adjuvant ALK+ NSCLC

1. Source: Evaluate Pharma; 2. Source: Roche; NSCLC=Non-Small Cell Lung Cancer
Gastrointestinal (GI) and Genitourinary (GU) cancers
First-in-class potential in multiple tumor types

Growth opportunities in 1L mUC and 1L HCC

**Tecentriq**
- Positive Ph 3 data in 1L mUC ✓
  Expected to be first CIT agent in chemo-eligible patients
- Ph 3 data in 1L HCC exp. 2019

**ipatasertib**
- Ph 3 data in mCRPC exp. 2020

GI/GU market growing to 34b USD by 2024¹

Further growth potential in early disease

<table>
<thead>
<tr>
<th>First in-class potential for Tecentriq in adjuvant MIBC and RCC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RCC adjuvant</strong></td>
</tr>
<tr>
<td>110k</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NMIBC</strong></th>
<th><strong>MIBC</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>150k</td>
<td>75k</td>
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</table>

<table>
<thead>
<tr>
<th><strong>1L</strong></th>
<th><strong>2L</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>50k</td>
<td>40k</td>
</tr>
</tbody>
</table>

Three ongoing trials in early GI/GU cancers

**IMbrave150**: 1L HCC ✓

**IPATENTIAL150**: mCRPC

1. Source: Evaluate Pharma; HCC=Hepatocellular Carcinoma; mUC=metastatic urothelial carcinoma; CIT=Cancer Immunotherapy; CRPC=Castration Resistant Prostate Cancer; RCC=Renal Cell Carcinoma; NMIBC=Non-Muscle Invasive Bladder Cancer; MIBC=Muscle Invasive Bladder Cancer

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¹. Source: Evaluate Pharma; HCC=Hepatocellular Carcinoma; mUC=metastatic urothelial carcinoma; CIT=Cancer Immunotherapy; CRPC=Castration Resistant Prostate Cancer; RCC=Renal Cell Carcinoma; NMIBC=Non-Muscle Invasive Bladder Cancer; MIBC=Muscle Invasive Bladder Cancer
Hematology
Building upon our leadership & experience with transformative medicines

Continuing to redefine the SOC in B-cell malignancies

Gazyva + Venclexta 1L CLL launch:
• Fixed dose, chemo free option for patients

Polivy 3L+ DLBCL launch, pivotal trial ongoing in 1L DLBCL:
• Off the shelf treatment with strong efficacy and safety profile

CD20 x CD3 bispecifics:
• Developing as monotherapy in later lines, rapidly moving into early line combinations

Expanding into new hematologic diseases

Venclexta launch in 1L AML:
• High unmet need in disease with few treatment options

Venclexta in pivotal trial in MM
~20% of MM patients with t(11:14) translocation

Key upcoming readouts in NHL, CLL

POLIVY
CD20 x CD3 bispecifics
POLARIX: 1L DLBCL
3L aNHL and FL

CD20 x CD3 TCB
mosunetuzumab
CLL 13%
DLBCL 17%
iNHL 37%
AML 9%
MM 17%
ALL 3%
MDS 7%

Key upcoming readouts in MM, AML

Venclexta launch in 1L AML:
• High unmet need in disease with few treatment options

Venclexta in pivotal trial in MM
~20% of MM patients with t(11:14) translocation

CANOVA: MM (t11:14)
MIRROS: R/R AML
idasanutlin

Gazyva + Venclexta
mosunetuzumab
CD20 x CD3 TCB

Datamonitor: incidence rates includes the 7 major markets (US, Japan, France, Germany, Italy, Spain, UK); CLL=Chronic lymphoid leukemia; DLBCL=Diffuse large B-cell lymphoma; iNHL=Indolent Non-Hodgkin's lymphoma; AML=Acute myeloid leukemia; MM=Multiple myeloma; MDS=Myelodysplastic syndrome; ALL=Acute lymphoblastic leukemia; Venclexta in collaboration with AbbVie
Hemophilia

Hemlibra provides a transformational advance for patients

Total HA market growing to USD 12bn by 2024

1 Source: Evaluate Pharma; PWHA=People with Hemophilia A; Source: Treated patients MORSE 2017 (prevalence), UKHCDO Annual Report 2016 and internal assumptions (treatment rate)
On the page, there are sections for *Onology / Hemaology* and *Neuroscience* along with *Immunology, Ophthalmology, and Infectious Diseases*. The content includes various cancers and diseases categorized under these fields.
Ulcerative Colitis (UC) and Crohn’s Disease (CD)
Potential for disease leading profile in markets with unmet need

IBD market

~1.3M IBD patients in US/EU5 with moderate-severe disease
- Average age of diagnosis: 15-30yrs old
- Use of targeted therapies is growing with new MOAs

Global IBD market growing to ~20b USD by 20241

Potential for improved efficacy
- High unmet need still in market with only 10-30% of patients achieving sustained remission and frequent surgical interventions
- Etrolizumab differentiated among integrin class by dual mode of action: blocking leukocyte trafficking (via α4β7) and lymphocyte retention (via αEβ7)

Best-class dosing profile
- Monthly SC administration

Key upcoming readouts:
- UC 2020: HIBISCUS I/II: TNF-naïve, induction (vs. Humira)
- GARDENIA: TNF-naïve, sustained remission (vs. Remicade)
- LAUREL: TNF-IR, maintenance
- HICKORY: TNF-IR, induction and maintenance
- CD 2021: BERGAMOT: moderate-to-severe CD

Lupus Nephritis (LN)

**Gazyva has the potential to be the first approved therapy in LN**

**Lupus Nephritis**

- **~165k patients** in US/EU5 with Lupus Nephritis
- **Systemic lupus erythematosus (SLE)**
- **~40%**
- **Lupus Nephritis (LN)**
- **~45% of patients with proliferative disease (Grade 3/4)**

**Diversity in clinical trials initiative**

- Lupus disproportionately affects women and minorities
- Approximately half of the patients in Ph2 NOBILITY trial were non-white

**Demonstrated efficacy in randomized Ph2 trial**

- Data to be presented at upcoming medical conference

**No approved therapies for LN in the US**

- >20% of patients currently progress to End Stage Renal Disease within 15 years

**Dosing convenience**

- Exploring q6m dosing after first year

**BTD submission**

- Actively engaging with health authorities about path forward

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1. Source: Roche; LN=Lupus Nephritis; SLE=Systemic lupus erythematosus; BTD=breakthrough therapy designation
Ophthalmology

Roche has the broadest Ph3 pipeline in retina

High unmet medical need in retinal diseases

• High treatment burden of anti-VEGF therapies in real world associated with suboptimal visual outcomes\(^1\)
• Growing market driven by aging population and incidence of diabetes

~9.7M patients
in US/EU5 with nAMD or DME

• Treatment rate in DME ~50%
• >2M additional patients in US/EU5 with RVO, where Lucentis is approved and treatment rates <50%

Total retina medical market USD ~10bn in 2018\(^2\)

faricimab, PDS

Opportunities for improved durability or efficacy

Key upcoming readouts in ophthalmology

Port Delivery System

faricimab

ARCHWAY: nAMD
YOSEMITE/RHINE: DME
TENAYA/LUCERNE: nAMD

1 F.G. Holz et al., Br J Ophthalmol 2015; 2 Evaluate Pharma; nAMD=neovascular age related macular degeneration; DME=diabetic macular edema; PDS=Port Delivery System with ranibizumab
Neuroscience and Rare Diseases

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- Autism
- Alzheimer’s
- NMOSD
Multiple Sclerosis (MS)

Ocrevus remains #1 approved therapy in the US; gaining share globally

**Total MS market USD ~23bn in 2018**

**Ocrevus annualized sales ~3.6b CHF**

- **Efficacy**: slowing progression of disease across RMS/PPMS
- **Safety**: >120k patients treated, no PML cases related to drug
- **Convenience**: dosing every 6 months
- **Access**: pricing strategy enables broad payer coverage

Source: 1. Symphony Health, rolling 3-month prescriber-based data, includes both naïve and switch patients 2. Evaluate Pharma; PML=Progressive multifocal leukoencephalopathy; RMS=Relapsing Multiple Sclerosis; PPMS=Primary Progressive Multiple Sclerosis
Spinal Muscular Atrophy (SMA)
Potential to be treatment of choice for majority of SMA patients

### Unmet need remains across SMA

<table>
<thead>
<tr>
<th>gene therapy</th>
<th>nusinersen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Durability, Administration</strong></td>
<td><strong>Burden of IT administration</strong></td>
</tr>
<tr>
<td>- Durability</td>
<td>- Especially significant with scoliosis</td>
</tr>
<tr>
<td>• Little data beyond 3 years</td>
<td>• Accumulation of repeat lumbar punctures</td>
</tr>
<tr>
<td>• Potentially confounded by follow-on therapy</td>
<td></td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td><strong>Safety</strong></td>
</tr>
<tr>
<td>• Acute serious liver injury warning</td>
<td>• Meningitis and hydrocephalus cases</td>
</tr>
<tr>
<td>• Systemic corticosteroid immunosuppression for ≥ 2 months</td>
<td></td>
</tr>
<tr>
<td><strong>Addressable population</strong></td>
<td><strong>Evidence in adults</strong></td>
</tr>
<tr>
<td>• Limited population</td>
<td>• Lack of pivotal trial data in patients</td>
</tr>
<tr>
<td>• Not approved &amp; limited data in pts &gt;2 years old (~90% of SMA)</td>
<td>• &gt; 9 years old at treatment initiation</td>
</tr>
</tbody>
</table>

~70% of U.S. SMA patients are not currently receiving disease modifying therapy

### risdiplam

**Oral therapy with best-in-class efficacy potential**
- Compelling efficacy seen in Type 1, despite advanced age
- Durably increases SMN throughout CNS and periphery
- Rapid treatment sparing need for IT & immunosuppression

**Strong Safety Profile**
- To date, no drug-related safety findings leading to withdrawal in any study

**Broader clinical trial program**
- Pre-symptomatic to older adults. Naïve & pre-treated.
- Ph3 RCT in 2-25 yr old Type 2/3 SMA reading out in 2019

- Filing for broad labels in 2019 (US) and 1H’20 (EU)
Huntington’s Disease (HD)

HTT-ASO has potential to be first disease modifying agent in HD

~80k patients in the US/EU with ‘Manifest’ HD (4x size of SMA)

HTT-ASO

Strong mechanistic hypothesis
- Demonstrated reduction of mHTT beyond target levels (singular mechanistic driver of disease)

First in disease potential
- No available therapies that prevent onset or slow progression. Ph 3 GENERATION HD1 trial actively recruiting patients; no other competitors in pivotal trials

Broad coverage of all Huntington’s alleles
- No additional genotyping required (lengthy, costly)

Convenient dosing
- Dosing q8w and q16w

HD market size estimated ~5bn USD¹

Source: 1. Roche internal estimate; mHTT=mutant Huntington protein; HTT-ASO licensed from IONIS Pharmaceuticals
Roche Pharma in China

Multiple policies issued to encourage drug innovation

Company in oncology
#4 multinational Pharma company overall\(^1\)

>3b CHF
annualized pharma sales
(HY growth +54%)

Full value chain
>3,500 Roche employees
(Re&D, Marketing, Medical, Manufacturing)

China Market Changes

REIMBURSEMENT

Herceptin, Avastin, Mabthera added to NRDL
1.4bn people covered by NRDL; 98% of healthcare spend under public insurance

REGULATORY SPEED

Alecensa China approval within 9 months of US

1. Source: IMS Hospital audits 2018; NRDL: National Reimbursement Drugs List
Doing now what patients need next