Cancer and Autoimmune Diseases

We are armed to fight
Forward Looking Statement

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OSE Immunotherapeutics: Leaders in Immunology

IMMUNO-ONCOLOGY

INFLAMMATION

VACCINES
# OSE Immunotherapeutics

*Delivering from Target to Clinic*

## Key Facts

<table>
<thead>
<tr>
<th>2012 - 2015</th>
<th>5 clinical assets in 2021</th>
<th>€42m raised through equity</th>
<th>€60m generated through partnerships</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Creation to IPO</em> EuroNext (OSE)</td>
<td>~70 FTEs</td>
<td></td>
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</tr>
</tbody>
</table>

### 1. Phase 3 asset: Tedopi®
- Positive Step-1 results in NSCLC *post-checkpoint* inhibitor
- Phase 3 Step-1 Primary *endpoint met*
- FDA/EMA discussions on best path to market to start in H1 2021

### 5. Clinical stage assets in 2021
- 3 *Fully* owned
- 2 * Partnered* with Boehringer Ingelheim and Servier

### 3. Fully owned assets approaching the clinic
- Funded to *maximize* value to stakeholders
### Complementary Platforms and Balanced Pipeline

<table>
<thead>
<tr>
<th>ASSET</th>
<th>TARGET</th>
<th>INDICATION</th>
<th>PRE-CLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>NEXT INFLECTION POINT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedopi®</td>
<td>Neoepitopes</td>
<td>NSCLC post CKI failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Potential regulatory filing: end of 2021 in pre-specified population</td>
</tr>
<tr>
<td>Tedopi®</td>
<td>Neoepitopes</td>
<td>Advanced pancreatic cancer</td>
<td></td>
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<td></td>
<td>Phase 2 read-out: 2022*</td>
</tr>
<tr>
<td>CoVepiT</td>
<td>Epitopes</td>
<td>Second Generation COVID-19 vaccine</td>
<td></td>
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<td>Phase 1 start: Q1 2021</td>
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<tr>
<td>FR104</td>
<td>CD28 antagonist</td>
<td>Auto-immune diseases &amp; Transplantation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phase 2 start: H2 2021</td>
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<tr>
<td>OSE-230</td>
<td>Anti-ChemR23 agonist</td>
<td>Resolution of inflammation</td>
<td></td>
<td></td>
<td></td>
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<td>Phase 1 start: H1 2022</td>
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<tr>
<td>OSE-279</td>
<td>Anti-PD-1</td>
<td>Niche indication</td>
<td></td>
<td></td>
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<td>Phase 1 start: H2 2021</td>
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<tr>
<td>CLEC-1</td>
<td>Myeloid checkpoint</td>
<td>Various cancers</td>
<td></td>
<td></td>
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<td>Phase 1 start: H2 2022</td>
</tr>
<tr>
<td>BiCKI® Bi-Functional Platform</td>
<td>T cells + Innovative targets</td>
<td>Various cancers</td>
<td></td>
<td></td>
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<td>Phase 1 start: H2 2022</td>
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<tr>
<td>PARTNERED</td>
<td></td>
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<tr>
<td>OSE-127</td>
<td>IL-7R antagonist</td>
<td>Ulcerative Colitis (OSE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Phase 2 read-out: H2 2022</td>
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<tr>
<td>OSE-127</td>
<td>IL-7R antagonist</td>
<td>SJögren's syndrome (SERVIER)</td>
<td></td>
<td></td>
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<td></td>
<td>Phase 2 read-out: H2 2022</td>
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<tr>
<td>BI 765063 (OSE-172)</td>
<td>SIRPα-CD47 antagonist</td>
<td>Solid Tumors</td>
<td></td>
<td></td>
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<td>Phase 1 read-out: Q3 2021</td>
</tr>
</tbody>
</table>

* COVID-19 Impact
Transforming OSE Immunotherapeutics for the Next Decade

Clear goals and objectives to deliver outstanding return to shareholders

- Immunology expertise validated by strong clinical data and partnerships
- First post-IPO capital injection to capture more in-house asset value
- Preparation for potential Tedopi® launch in lung cancer (NSCLC)
- Moving to a fully-fledged biotech model
- Laser-focused prioritization of R&D resources
- Leveraging current and future partnerships
An Executive Team with Complementary Expertises and Proven Track Record

<table>
<thead>
<tr>
<th>Competencies</th>
<th>Immunology</th>
<th>Leading organizational growth</th>
<th>Clinical development</th>
<th>Partnerships</th>
<th>Fund raising</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominique Costantini</td>
<td>![Image]</td>
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</tr>
</tbody>
</table>

- **Alexis Peyroles**
  - Head of Development
  - Immunology:  
  - Leading organizational growth: ✓
  - Clinical development: ✓
  - Partnerships: ✓
  - Fund raising: ✓

- **Dominique Costantini**
  - Chief Scientific Officer
  - Immunology:  
  - Leading organizational growth: ✓
  - Clinical development: ✓
  - Partnerships: ✓
  - Fund raising: ✓

- **Nicolas Poirier**
  - Chief Executive Officer
  - Immunology:  
  - Leading organizational growth: ✓
  - Clinical development: ✓
  - Partnerships: ✓
  - Fund raising: ✓

**Sanofi Aventis**
- 45 publications
- 30 patents (patent families)

**Effimune**
- 10 products registered including 3 at FDA
- 10 patents (patent families)

**Previously HMR**
130k patient opportunity in advanced NSCLC post-Immune Checkpoint Inhibitors
Tedopi®

Proprietary combination
(9 optimized neoepitopes
+ 1 epitope giving universal T
helper response)

Restores *immuno-surveillance*
of cancer cells in HLA-A2
positive responder patients

Induces early T cell
*memory* responses

Strong patent family plus
orphan status in the US

NEOEPITOPES / HLA / TCR binding*:
- **Mandatory** to activate cytotoxic T-cell response
- Neoepitopes: Small peptides deriving from tumor specific antigens expressed in various cancers
- 1st T-lymphocyte *activation* signal

*T* Major Histocompatibility Complex
1 Garrido et al 2012;
2 Mimura et al 2011- Sabapathy K et al 2008
Identifying Epitopes to Trigger Optimal Immunogenicity

Based on 10 Years of R&D

1. **Epitope prediction**
   - In silico motif analysis

2. **Affinity determination**
   - In vitro capture assays

3. **Immunogenicity**
   - In vivo T cell activation
Tedopi® Demonstrated Overall Survival Benefit in NSCLC post-CKI in Phase 3 Step-1

**Overall Survival Benefit Clinically Meaningful**
In the Targeted Per Protocol Population

**Post Progression Survival ITT Population**
Benefit of Tedopi® Continued Beyond Progression

**Median OS**
Tedopi® 11.1 months vs SoC 8.7 months
HR 0.57 / p-value=0.04

**Median Post Progression Survival**
Tedopi® 7.5 months vs SoC 4.4 months
HR 0.51 / p-value=0.02

Step-1 Primary endpoint achieved: One year survival rate of 46% for Tedopi® patients*

*Cut-off 26FEB2020 before COVID-19 impact: 103 patients with one year follow-up for Step-1, 210 patients randomized in total
ClinicalTrials.gov Identifier: NCT02654587
G.Giaccone et al., ESMO 2020
Tedopi® Proved Safe and Provided Enduring Quality of Life Positive Benefit/Risk vs Standard of Care

Significant Increase in Time to ECOG deterioration

- Median Time to ECOG Deterioration
  - Tedopi® 8.4 months vs SoC 4.4 months
  - HR 0.44 / p-value=0.002

Significantly Safer than Standard of Care

<table>
<thead>
<tr>
<th></th>
<th>Tedopi® (n=63)</th>
<th>Standard of Care (SoC) (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All grades n (%)</td>
<td>Severe* G3-4 n (%)</td>
</tr>
<tr>
<td>All Drug-Related Aes</td>
<td>50 (79)</td>
<td>9 (14)</td>
</tr>
<tr>
<td>Injection site reaction**</td>
<td>35 (56)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>10 (16)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Asthenia</td>
<td>9 (14)</td>
<td>-</td>
</tr>
<tr>
<td>Cytokine release syndrome</td>
<td>7 (11)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Alopecia</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Decrease appetite</td>
<td>2 (3)</td>
<td>-</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2 (3)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Anemia</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nausea</td>
<td>2 (3)</td>
<td>-</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5 (8)</td>
<td>-</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>1 (2)</td>
<td>-</td>
</tr>
</tbody>
</table>

ECOG Performance status evaluates the performance from individual and includes 5 Grade (Grade 1 is fully active to 5 is dead)

G.Giaccone et al., ESMO 2020

Cut-off 26FEB2020 before COVID-19 impact; Safety set 100 patients (excluded 3 patients not treated); *p< 0.001
**Injection site reaction as high-level term for injection site pain, nodular erythema, induration, inflammation, pain, pruritus

G. Giaccone et al., ESMO 2020
Tedopi® Market Opportunity

For Non-Small Cell Lung Cancer (NSCLC) after Checkpoint Inhibitor Failure

Source: WHO International Agency for Research on Cancer – 2020 Lung Fact Sheet
### Tedopi® Commercial Strategy – Maximizing Return to Shareholders

#### OSE Flexible Approach to Commercialization

**Option 1 - PARTNER**
- Maximizing peak sales through *partnership*, and releasing management time for earlier-stage assets

**Option 2 - DIRECT**
- Maximizing profitability through OSE *dedicated NSCLC* sales force
- +25 FTE in the US | +30 FTEs in Europe

#### Commercialization options to be evaluated during 2021
- Additional clinical indications planned

---

#### Next Regulatory Steps in NSCLC Post-CKI

**Q1 2021**
- Collection of data on *additional* 100 NSCLC patients from Tedopi® Phase 3 (Step-2 interrupted due to COVID-19)
- Total data on around *200 patients*

**Q2 2021**
- FDA/EMA *pre-approval* discussions in a pre-specified sub-population of interest

**End 2021**
- Potential *FDA/EMA submission* following pre-approval feedback
- *Launch* of commercialization strategy

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*COVID-19 impact to be evaluated
103 patients with one year follow-up for Step-1
More than 200 patients randomized in total
CoVepiT

2\textsuperscript{nd} generation COVID-19 vaccine

Multi-Target T cell responses against COVID-19
(provides long immune memory, anticipates viral mutation)
CoVepiT to Add T Cell Memory to B Cell Response for COVID-19

Viral clearance requires T cell stimulation

**B Cell – Humoral Response**

**PROS**
- **Validated** concept
- Large *global* manufacturing capacity

**CONS**
- **Unknown** power and durability of immune response
- Manufacturing/cold chain challenges (esp. mRNA vaccines)
- **Uncertain** protection in immunocompromised responders
- Virus may evade by evolution/mutation
- Predominant focus on *spike proteins*

**T Cell – Cellular Response**

**PROS**
- Fast and **potent** immune response
- Stimulates direct *T cell attack* against COVID-19
- **Universal** – supplements all vaccine types
- **Addresses and anticipates** viral evolution/mutation
- Synergistic activity, ideal for people with low immune system or low immune response to traditional/mRNA vaccines

**CONS**
- **Validated** approach at pre-clinical level against viruses, but *no* vaccine approved yet
CoVepiT: Second Generation Multi-Epitope CD8+ T Cell Vaccine Against COVID-19
Confirmed *In vivo* and Human *Ex vivo* Results

*Broad and diversified* targeting of most conserved epitopes (12 epitopes CD8+ T cells against 11 conserved viral proteins and one CD4+ T cell epitope)

CoVepiT T cell epitopes *induce in vivo* tissue-resident memory T cell sentinels (Trm) *in lung*

Efficacy validated in human *ex vivo* data

- Potent CD8+ T cells against all selected epitopes – demonstrated in man
- Potential to target MERS and SRAS (and future coronavirus threats)

CoVepiT ideally *positioned for* ~25m immunocompromised and the 135m patients 65+ in the US and Europe

Start of clinical trial scheduled for Q1 2021
BI 765063 (OSE-172)
SIRPα-CD47 in Solid Tumors in collaboration with
Boehringer Ingelheim
BI 765063 (OSE-172) Controlling the “Don’t-Eat-Me” Signal Without CD47 Antagonists Potential Drawbacks

**CD47- SIRPα interaction blocks immune cell activation leading to tumor cell growth**

**BI 765063 : stops the “Don’t Eat Me” mechanism by which tumors evade immune detection and allows T lymphocytes to enter the tumor core**

Gauttier et al ; JCI 2020  Selective SIRPα blockade reverses tumor T cell exclusion and overcomes cancer immunotherapy resistance
### BI 765063 (OSE-172)
**Strong Rational for Improved Safety and Synergy with Anti-PD-1**

#### Pre-clinical evidence differentiates SIRPα blockade and CD47 blockade

<table>
<thead>
<tr>
<th></th>
<th>Anti-CD47</th>
<th>Anti-SIRPα BI 765063</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad/restricted expression</td>
<td>Broad</td>
<td>Restricted to cells of the myeloid lineage</td>
<td>Limited side effects expected</td>
</tr>
<tr>
<td>Interaction with SIRPγ</td>
<td>Unknown</td>
<td>BI 765063 is SIRPα specific</td>
<td>SIRPγ necessary for T cell responses</td>
</tr>
<tr>
<td>Dosing frequency</td>
<td>High</td>
<td>Low</td>
<td>Limited side effects expected</td>
</tr>
<tr>
<td>Interference with T cell responses</td>
<td>Negative</td>
<td>Positive</td>
<td>Higher efficacy in solid tumors in synergy with Anti-PD-1 expected</td>
</tr>
<tr>
<td>Safety signals</td>
<td>Acute anemia, Thrombocytopenia</td>
<td>No hematotoxicity</td>
<td>Higher therapeutic window expected</td>
</tr>
</tbody>
</table>

Gauttier et al.; JCI 2020  Selective SIRPα blockade reverses tumor T cell exclusion and overcomes cancer immunotherapy resistance
BI 765063 (OSE-172) Potential Best-in-Class Asset in Blockbuster Market

Boehringer Ingelheim Deal Structure

- **Up to €1.1bn** in milestones
- **€30m** received
  - Received
  - Additional potential
  + High-single digit to low teens royalties on Global Sales

Market events raise expectations and valuations for the CD47 pathway

- **ALX ONCOLOGY**
- **$3.0bn** Market Cap
- **$4.9bn** Acquisition by Gilead
OSE-127 in Ulcerative Colitis and Sjögren’s Syndrome in collaboration with
OSE-127 - Differentiated MoA as Full IL-7 Receptor Antagonist

License Option to Servier after Phase 2

A collaborative deal underpinning differentiated science

Up to €272m in milestones

€20m received

- High-single digit to low teens royalties on global sales
OSE-127 – Ulcerative Colitis

License Option to SERVIER after Phase 2

Ulcerative Colitis developed by OSE

- UC affects **3.3 million patients** in US, Europe and Japan
- ~50% UC patients “moderate to severe”, requiring methotrexate, corticosteroids, anti-TNFα, JAK etc.
- Despite broad options, *remission rates* are of only 25-30%² leaving most patients without satisfactory treatment
- **15% of patients**³ fail to respond to all therapies and get surgery as last option

Phase 2 trial started in December 2020

Current standard of care largely calls on two main therapeutics classes with a total market of $6.3 billions¹

- 2019 Global sales in Ulcerative Colitis
  - $1,8bn
  - $1,2bn
  - $3,1bn

1 – evaluate pharma
3 - Scientific Reports volume 10, Article number: 12546 (2020)
OSE-127 – Sjögren’s Syndrome

License Option to SERVIER after Phase 2

Sjögren’s syndrome developed by SERVIER

- **3rd most common** autoimmune disease affecting the body’s moisture-producing glands, lungs, kidney and nervous system. Often found in patients suffering from Rheumatoid Arthritis and Systemic Lupus Erythematosus.

- Affects ~600,000 patients in US, EU and Japan, including over 50% in US.

- OSE-127 will target ~40% of moderate-to-severe patients with ESSDAI scores over 5.

- **Well identified** patient population; over 75% of Sjögren’s syndrome patients are treated.

- **Current treatment** depends on:
  - Genericized cevimeline hydrochloride (Exovac)
  - Lubricants / topicals
  - Off-label use of B cell modulators (Rituxan, Benlysta)

- Sole approved drug, cevimeline, **proven to** increase salivary flow; dosed 3 times day (TID).

Phase 2 trial to start in Q1 2021
Proprietary Early-Stage Assets: Creating Significant Value Over the Next Three Years and Beyond

**FR104**
- **CD28 antagonist** in autoimmune diseases & transplantation
- Phase 1/2 in Kidney Tx
  - Started in **Dec 2020**
  - Phase 2 in AID Start **H2 2021**

**OSE-230**
- Anti-ChemR23 agonist
- Resolution of inflammation
- Phase 1 Start **H1 2022**

**CLEC-1**
- **Blocking myeloid** immune checkpoint
- New “Don’t-eat-me” signal
- Phase 1 Start **H2 2022**

**BiCKI® Bi-Functional Platform**
- **Innovative** bifunctional anti-PD1 antibody backbone platform
- OSE-279 (Anti-PD-1 mAb)
  - Phase 1 Start **H2 2021**

OSE IMMUNOTHERAPEUTICS
Phase 1 results: Selective CD28 antagonist FR104 persistently reduces antibody responses

- **Good safety** - demonstrated
  - Absence of clinical or biological events
  - No change in total lymphocyte counts
  - No cytokine elevation
- Controls model IgG (anti-KLH) response for up to 57 days
- Controls T follicular helper and IgG responses
- Tfh cells correlated with autoimmune diseases activity
FR104 – Ambitious Development Plan in 2021

Phase 1/2 in kidney allotransplantation

- In ~10 Kidney transplant recipients
  - End-points: Safety, Tolerability, PK, Efficacy
  - Translational studies in blood and sera
- First Read-out expected in H1 2022

Phase 2 Graves’ disease (Autoimmune niche indication) to start in H2 2021

- Autoimmune disorder affecting 4 million patients\(^1\) in the US/EU and leading to hyperthyroidism
- Mostly affect 30-50 year-old women
- Often leads to cardiologic complications and osteoporosis
- Phase 2 to be conducted in around 80 patients
- Read-out expected in H1 2023

---

\(^{1}\) NIH Data estimating that Graves affects 1 in 200 people (https://medlineplus.gov/genetics/condition/graves-disease/#frequency)
OSE-230 – Resolving Inflammation is an Active Immune Process

During chronic inflammation

Dying neutrophils send out inflammatory signals that are important in maintaining chronic inflammation & recruiting Lymphocytes

With ChemR23 agonistic mAbs

Restoration of homeostasis

OSE-230-mediated activation of resident macrophages induces efferocytosis of apoptotic neutrophils, removing further inflammatory signals

Start of clinical trial scheduled for 2022
OSE-230 – Pre-Clinical Data Demonstrate Strong Effect on Neutrophils and Leucocytes

**Higher ChemR23 expression in anti-TNFα refractory patients**

**OSE-230 significantly reduces neutrophils and leucocytes in inflammatory models in monkeys**

[Graphs showing comparison of neutrophils and leucocytes before and after anti-TNFα treatment in Ulcerative Colitis and Crohn Disease]
CLEC-1

Blocking myeloid immune checkpoint from delivering another “Don’t-eat-me” signal

Start of clinical trial scheduled for 2022
CLEC-1 - Pre-Clinical Data Demonstrate Strong Rational for CLEC-1 Inhibition in Combination to Chemotherapy

CLEC-1L surges on tumor cells after chemotherapy

CLEC-1 deficiency impairs tumor growth in combination with chemotherapy

CLEC-1 antagonist mAbs increase tumor cells ADCP by human macrophages (shown) and tumor cell phagocytosis by dendritic cells (not shown)

Poster #212 SITC 2020 – “CLEC-1 is a novel myeloid immune checkpoint for cancer immunotherapy controlling damaged and tumor cells phagocytosis”
BiCKI® Bi-Functional Platform in Oncology

OSE-279: Humanized Anti-PD1 mAb blocking binding of PD-L1 and PD-L2

- **Anti PD-1 Backbone**
  - Blocks PD-1 inhibitory signal
  - Delivers drug to tumor microenvironment (TME) on PD-1-expressing T cells

OSE-279 Phase 1 to start in H2 2021
BiCKI® OSE-279/IL-7 Show Strong Synergistic Effect in Multiple Solid Tumor Types

BiCKI®IL-7 promotes human TILs IFNg secretion in ex vivo organoid model
Summary
Transitioning from World-Class Science to Commercial Readiness

- Adjusting strategy to prepare for proprietary pipeline acceleration and next phase of growth
- World leading research capabilities having delivered 3 platforms with mid-late stage assets
- Tedopi® in NSCLC post-CKI showed strong clinical benefit in Phase 3 Step 1–Potential FDA/EMA filing by end of 2021 and additional clinical indications planned
- Highly differentiated COVID-19 vaccine candidate for ~160m immuno-compromised or 65+ groups in US/Europe, anticipates virus evolution/mutation
- Proprietary early-stage assets with 3 programs to enter the clinic in 2022-23 in blockbuster indications
- Strong partnerships with Boehringer Ingelheim and Servier generating substantial revenues to reduce cash burn and risk
Financial Visibility and Capital Structure

Shareholding structure

- Founders, Management, Board and Employees: 38%
- Institutional Investors and Retail: 62%

Financial visibility and share price

- Number of outstanding shares: 17,983,038
- Share price January 8th, 2021: 8.02 Euros
- Latest fund raising (Nov 2020): 18.6 millions Euros
- Financial visibility until Q1 2022
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