DARWIN 2
Final filgotinib monotherapy results

11 August 2015
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1. Filgotinib: first-in-class oral in RA
2. Transformational CF therapies
3. Fully-owned Ph2 programs in IBD/IPF
4. Platform to fill pipeline
5. Strong financials & partnerships
What are patients looking for in RA treatment?

- Oral administration
- Highly efficacious on patient relevant parameters (ACR50, ACR70, DAS28 remission)
- Rapid onset of action
- Safe & well tolerated
Filgotinib, a new mode of action
JAK1 discovered by us as target for bone & joint disease

|------|------|------|------|------|------|------|------|------|------|------|

- **JAK1 discovered using SilenceSelect®**
- **lead optimization**
- **compound screening**
- **development**
- **PCC nomination**
- **Start PoC**
- **Start Ph2A**
- **Deal with AbbVie**
- **Start Phase I trial**
- **PoC results**
- **Start Ph2B**
- **DARWIN final Ph2B results**
- **AbbVie decision period**
Selectivity matters
Filgotinib is the selective JAK1 inhibitor

Ratio JAK1/JAK2 in human whole blood assay

Hb recovery¹

anemia

Conclusions DARWIN 2
After 12 weeks of treatment

- Primary and key efficacy endpoints achieved
- High ACR and DAS28(CRP) responses
- Fast onset within one week
- Safety profile consistent across all filgotinib RA studies
Competitor monotherapy data
At week 24

% responders

Note: data reported in listed publications, not resulting from head-to-head studies.
Key eligibility criteria

• Inclusion:
  ➢ diagnosis of RA for at least 6 months (2010 ACR/EULAR criteria of RA and ACR functional class I-III)
  ➢ ≥6 SJC (66 joint count) and ≥8 TJC (68 joint count)
  ➢ screening serum CRP ≥0.7 x ULN*
  ➢ inadequate response to MTX, MTX wash-out at least 4 weeks prior to enrolment

• Exclusion:
  ➢ current therapy with any conventional DMARD, except anti-malarials
  ➢ current or previous RA treatment with a biologic DMARD

* ULN = 9 mg/L
Patient disposition

Screenings N=635

Randomized N=287

Not eligible at screening N=348

Randomized & exposed N=283

Not exposed N=4

W0-12

Placebo N=72

50 mg N=72

100 mg N=70

200 mg N=69

W13-24

100 mg N=65

50 mg N=52

100 mg N=15

100 mg N=67

200 mg N=66
Baseline demographics
Even distribution over dose groups

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>50 mg</th>
<th>100 mg</th>
<th>200 mg</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean, years</td>
<td>52</td>
<td>52</td>
<td>53</td>
<td>52</td>
<td>52</td>
</tr>
<tr>
<td>Female</td>
<td>78%</td>
<td>86%</td>
<td>76%</td>
<td>87%</td>
<td>82%</td>
</tr>
<tr>
<td>Duration of RA, mean, years</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>DAS28(CRP), mean</td>
<td>6.2</td>
<td>6.0</td>
<td>6.2</td>
<td>6.1</td>
<td>6.1</td>
</tr>
<tr>
<td>CRP, mean, mg/L</td>
<td>35</td>
<td>25</td>
<td>26</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>TJC68, mean</td>
<td>25</td>
<td>25</td>
<td>27</td>
<td>26</td>
<td>26</td>
</tr>
<tr>
<td>SJC66, mean</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>16</td>
<td>17</td>
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</tbody>
</table>
## Early discontinuations
### Week 0-24, number of patients

<table>
<thead>
<tr>
<th></th>
<th>W0-12 Placebo (N=72)</th>
<th>50 mg (N=72)</th>
<th>100 mg (N=70)</th>
<th>200 mg (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>7</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Safety</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>W13-24 Placebo to 100 mg responders only (N=52)</th>
<th>100 mg (N=67)</th>
<th>200 mg (N=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Safety</td>
<td>1</td>
<td>2</td>
<td>1</td>
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</tbody>
</table>
Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.

*: p<0.05; **: p<0.01; ***: p<0.001 (up to week 12)
ACR20
ITT-NRI

% responders

<table>
<thead>
<tr>
<th>Placebo</th>
<th>50 mg</th>
<th>100 mg</th>
<th>200 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>67</td>
<td>67</td>
<td>72</td>
</tr>
<tr>
<td>57</td>
<td>77</td>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>

*: p<0.05; **: p<0.01; ***: p<0.001 (at week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.
ACR50
ITT-NRI

% responders

*: p<0.05; **: p<0.01; ***: p<0.001 (at week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12
ACR70
ITT-NRI

% responders

*: p<0.05; **: p<0.01; ***: p<0.001 (at week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.
ACR responses
ITT-NRI, at week 24

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12
DAS28(CRP) ITT-LOCF

mean CFB

*: p<0.05; **: p<0.01; ***: p<0.001 (up to week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.
DAS28(CRP)

Patients switching to 100 mg/day

mean CFB

Week

Placebo to 100 mg (N=66)  50 mg to 100 mg (N=15)
Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.
DAS28(CRP)

ITT-LOCF: remission rate & low disease activity

% responders

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Remission (%)</th>
<th>Low disease activity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>50 mg</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>100 mg</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>200 mg</td>
<td>28</td>
<td>17</td>
</tr>
<tr>
<td>50 mg</td>
<td>17</td>
<td>19</td>
</tr>
<tr>
<td>100 mg</td>
<td>29</td>
<td>21</td>
</tr>
<tr>
<td>200 mg</td>
<td>19</td>
<td>19</td>
</tr>
</tbody>
</table>

*: p<0.05; **: p<0.01; ***: p<0.001 (at week 12)

Subjects who switch treatment at week 12 are handled as if they discontinued at week 12.
### Overview safety endpoints
Week 0-24, number of patients

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<tr>
<th></th>
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<th>200 mg (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE AE</td>
<td>28</td>
<td>29</td>
<td>23</td>
<td>30</td>
</tr>
<tr>
<td>Serious TE AE</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Serious TE infection</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>W13-24 Placebo to 100 mg (N=65)</th>
<th>50 mg responders only (N=52)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>TE AE</td>
<td>10</td>
<td>16</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Serious TE AE</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Serious TE infection</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
TEAEs of special interest
Week 0-24

- No cases of MACE
- All infections – no dose response
  - filgotinib (16%) versus PBO (10%) at week 12
    - mainly urinary tract infections & upper respiratory tract infections
  - 1 pneumonia (200 mg)
  - 1 herpes zoster (50 mg)
- No opportunistic infections, no tuberculosis
- No malignancies, no lymphoma
- No death
Hemoglobin
Data up to W24

Responder: at least 20% drop in TJC68 and SJC66 versus baseline
LDL & HDL in DARWIN 1 & 2
200 mg QD

mean % CFB

DARWIN 1

DARWIN 2

Week

200 mg LDL
200 mg HDL

Week

200 mg LDL
200 mg HDL
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Measure</th>
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</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>increase up to 4%</td>
</tr>
<tr>
<td>Platelets</td>
<td>decrease towards mid normal value</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>no drop</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>decrease towards mid normal value</td>
</tr>
<tr>
<td>Creatinine</td>
<td>increase up to 13%</td>
</tr>
<tr>
<td>ALT</td>
<td>no CTCAE gr 3-4 on treatment</td>
</tr>
<tr>
<td>Lipids</td>
<td>increase of HDL (up to 24%) &amp; LDL (up to 17%)</td>
</tr>
<tr>
<td>Male hormones</td>
<td>no clinically meaningful changes</td>
</tr>
</tbody>
</table>
Conclusions – efficacy
Week 0-24

- Fast onset of action
- Dose response
- Sustained high level of ACR20 and ACR50 response
- Further increase in efficacy over 24 weeks
  - ACR70 response
  - DAS28 CRP remission
  - DAS28 CRP low disease activity
Conclusions – safety
Week 0-24

- Safety profile consistent with previous data
- Low drop out, SAE and serious infection rates
- Similar incidence in TEAEs and SAEs between filgotinib and placebo
- Higher incidence in infections on filgotinib, no dose dependency
- Stabilization of initial decrease in neutrophils and initial increase in creatinine, HDL & LDL
- Confirmation of differentiated safety profile in RA:
  - increase in hemoglobin, no drop in lymphocytes
  - no increase in liver function tests
Filgotinib in coming months

- AbbVie licensing decision coming up
- DARWIN 3 long term extension study in RA continues
- Start Phase 3 in RA in 2016
- FITZROY Phase 2 study in Crohn’s disease
  - 10 week primary endpoint results expected before year end 2015
  - 20 week final results expected in Q1 2016
Thank you

- Patients
- Investigators
- Team
- AbbVie