TAK-279 (TYK2 inhibitor)
Investor Call on Phase 2b Psoriasis Data

March 18th, 2023 ET / March 19th, 2023 JST
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AGENDA

Today’s Topics

1. Efficacy and safety results from the randomized, double-blind, placebo-controlled phase 2b trial of TYK2 inhibitor NDI-034858* in moderate-to-severe psoriasis

Graham Heap, MBBS, PhD
Vice President Global Program Leader, R&D

Panelists

Andy Plump
President, R&D

Uthra Sundaram
Executive Vice President & Head of Global Product & Launch Strategy, Global Portfolio Division

Graham Heap
Vice President Global Program Leader, R&D

2. Q&A Session

*NDI-034858 now known as TAK-279
TYK2 is a key component of the JAK–STAT signaling pathway. Increased activation of proinflammatory enzymes in this pathway is associated with several autoimmune diseases, including psoriasis.

TAK-279 is a highly selective oral allosteric TYK2 inhibitor.

<table>
<thead>
<tr>
<th>Biological Binding</th>
<th>K&lt;sub&gt;d&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYK2–JH2 binding</td>
<td>0.034 nM</td>
</tr>
<tr>
<td>JAK1–JH2 binding</td>
<td>5000 nM</td>
</tr>
<tr>
<td>Biochemical selectivity (fold)</td>
<td>1,470,588</td>
</tr>
</tbody>
</table>

Nimbus proprietary structure based computational modeling

JAK, Janus kinase; K<sub>d</sub>, dissociation constant; IFN, interferon; IL, interleukin; STAT, signal transducer and activator of transcription; TYK, tyrosine kinase
Study design: NCT04999839 (US, Canada)

Key eligibility criteria:
- Age 18–70 years
- Plaque psoriasis for ≥6 months
  - PASI ≥12
  - PGA ≥3
  - BSA ≥10%
- Candidate for phototherapy or systemic therapy

Primary endpoint:
- PASI 75 at Week 12

Secondary endpoints:
- PGA 0/1 at Week 12
- PASI 90 at Week 12
- PASI 100 at Week 12
- Change from baseline in DLQI at Week 12

BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PGA, Physician’s Global Assessment; QD, once daily; R, randomization
NCT04999839: https://clinicaltrials.gov/ct2/show/NCT04999839
Study disposition

Assessed for eligibility (n=443)

Screen failure (n=184)
Inclusion/exclusion criteria not met (156; 35.2%)

Randomized and dosed (n=259)

Placebo (n=52)

TAK-279 2 mg (n=50)

TAK-279 5 mg (n=52)

TAK-279 15 mg (n=53)

TAK-279 30 mg (n=52)

Discontinued study (n=9; 17.3%)
• Withdrawal by patient (n=6)
• LTFU (n=2)
• AEs (n=1)

Discontinued study (n=8; 16.0%)
• Withdrawal by patient (n=5)
• Lack of efficacy (n=1)
• AEs (n=1)
• Sponsor request (n=1)

Discontinued study (n=7; 13.5%)
• Withdrawal by patient (n=3)
• LTFU (n=2)
• AEs (n=1)
• Other (n=1)

Discontinued study (n=7; 13.2%)
• LTFU (n=4)
• Withdrawal by patient (n=2)
• AEs (n=1)

Discontinued study (n=5; 9.6%)
• Withdrawal by patient (n=2)
• Physician decision (n=1)
• LTFU (n=1)
• AEs (n=1)

Completed 12 weeks (n=43)

Completed 12 weeks (n=42)

Completed 12 weeks (n=45)

Completed 12 weeks (n=46)

Completed 12 weeks (n=47)

AE, adverse event; LTFU, lost to follow-up
## Demographics and baseline disease characteristics

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n=52)</th>
<th>TAK-279 2 mg QD (n=50)</th>
<th>TAK-279 5 mg QD (n=52)</th>
<th>TAK-279 15 mg QD (n=53)</th>
<th>TAK-279 30 mg QD (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>48.8 (12.7)</td>
<td>45.8 (14.2)</td>
<td>45.1 (13.6)</td>
<td>46.2 (13.0)</td>
<td>48.5 (11.4)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>31 (59.6)</td>
<td>38 (76.0)</td>
<td>41 (78.8)</td>
<td>34 (64.2)</td>
<td>33 (63.5)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>44 (84.6)</td>
<td>43 (86.0)</td>
<td>40 (76.9)</td>
<td>46 (86.8)</td>
<td>42 (80.8)</td>
</tr>
<tr>
<td>Asian</td>
<td>5 (9.6)</td>
<td>3 (6.0)</td>
<td>7 (13.5)</td>
<td>2 (3.8)</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Black/African American</td>
<td>2 (3.8)</td>
<td>4 (8.0)</td>
<td>4 (7.7)</td>
<td>3 (5.7)</td>
<td>4 (7.7)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.9)</td>
<td>0</td>
<td>1 (1.9)</td>
<td>2 (3.8)</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Weight, kg, mean (SD)</td>
<td>88.4 (15.8)</td>
<td>93.9 (16.7)</td>
<td>90.4 (18.7)</td>
<td>92.7 (16.8)</td>
<td>90.0 (18.3)</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>31.3 (5.1)</td>
<td>31.2 (5.2)</td>
<td>30.5 (5.7)</td>
<td>32.0 (4.9)</td>
<td>30.4 (5.4)</td>
</tr>
<tr>
<td>Psoriasis duration, years, mean (SD)</td>
<td>12.7 (10.5)</td>
<td>13.8 (10.8)</td>
<td>14.8 (10.7)</td>
<td>17.6 (14.6)</td>
<td>17.4 (11.1)</td>
</tr>
<tr>
<td>PASI score, mean (SD)</td>
<td>18.3 (8.1)</td>
<td>18.4 (6.8)</td>
<td>18.6 (6.1)</td>
<td>15.5 (4.5)</td>
<td>17.6 (6.2)</td>
</tr>
<tr>
<td>PGA score, mean (SD)</td>
<td>3.2 (0.4)</td>
<td>3.4 (0.5)</td>
<td>3.3 (0.5)</td>
<td>3.2 (0.4)</td>
<td>3.2 (0.4)</td>
</tr>
<tr>
<td>3 (moderate), n (%)</td>
<td>41 (78.8)</td>
<td>30 (60.0)</td>
<td>34 (65.4)</td>
<td>40 (75.5)</td>
<td>42 (80.8)</td>
</tr>
<tr>
<td>4 (severe), n (%)</td>
<td>11 (21.2)</td>
<td>20 (40.0)</td>
<td>18 (34.6)</td>
<td>13 (24.5)</td>
<td>10 (19.2)</td>
</tr>
<tr>
<td>BSA, mean (SD)</td>
<td>21.3 (13.6)</td>
<td>24.9 (15.5)</td>
<td>22.6 (12.1)</td>
<td>18.3 (10.3)</td>
<td>22.2 (14.3)</td>
</tr>
<tr>
<td>DLQI score, mean (SD)</td>
<td>12.4 (7.0)</td>
<td>10.3 (6.2)</td>
<td>12.8 (7.5)</td>
<td>11.9 (7.1)</td>
<td>12.5 (6.9)</td>
</tr>
<tr>
<td>Bioexperienced, n (%)</td>
<td>8 (15.4)</td>
<td>8 (16.0)</td>
<td>8 (15.4)</td>
<td>9 (17.0)</td>
<td>8 (15.4)</td>
</tr>
</tbody>
</table>

BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PGA, Physician’s Global Assessment; QD, once daily; SD, standard deviation
Patients achieving PASI 75, 90 or 100 at Week 12

**NRI analysis**

<table>
<thead>
<tr>
<th>Proportion of patients achieving PASI scores</th>
<th>Placebo (n=52)</th>
<th>TAK-279 2 mg QD (n=50)</th>
<th>TAK-279 5 mg QD (n=52)</th>
<th>TAK-279 15 mg QD (n=53)</th>
<th>TAK-279 30 mg QD (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASI 75</td>
<td>5.8%</td>
<td>8.0%</td>
<td>21.2%</td>
<td>45.3%</td>
<td>46.2%</td>
</tr>
<tr>
<td>PASI 90</td>
<td>0.0%</td>
<td>2.0%</td>
<td>*</td>
<td>**</td>
<td>***</td>
</tr>
<tr>
<td>PASI 100</td>
<td>0.0%</td>
<td>9.6%</td>
<td>*</td>
<td>15.1%</td>
<td>32.7%</td>
</tr>
</tbody>
</table>

p values from a Cochran-Mantel-Haenszel test, with prior biologic treatment included as a stratification factor, comparing the proportion of patients in the treatment group versus placebo. For secondary endpoints (PASI 90 and PASI 100), p values are nominal: *p<0.05; **p<0.005 ***p<0.001

Modified intent-to-treat (mITT) analysis set: all patients who were randomized and received at least one dose of study treatment

CI, confidence interval; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; QD, once daily
Representative PASI 100 response with TAK-279 30 mg QD

Baseline

Week 4

Week 12

PASI, Psoriasis Area and Severity Index; QD, once daily
Patients achieving PGA 0/1 or PGA 0 at Week 12

NRI analysis

<table>
<thead>
<tr>
<th>Treatment</th>
<th>PGA 0/1</th>
<th>PGA 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=52)</td>
<td>3.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>TAK-279 2 mg QD (n=50)</td>
<td>10.0%</td>
<td>2.0%</td>
</tr>
<tr>
<td>TAK-279 5 mg QD (n=52)</td>
<td>26.9%</td>
<td>9.6%</td>
</tr>
<tr>
<td>TAK-279 15 mg QD (n=53)</td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>TAK-279 30 mg QD (n=52)</td>
<td></td>
<td>*</td>
</tr>
</tbody>
</table>

* p values from a Cochran-Mantel-Haenszel test, with prior biologic treatment included as a stratification factor, comparing the proportion of patients in the treatment group versus placebo. For secondary endpoints (PGA 0/1), p values are nominal: *p<0.001; PGA 0: post hoc analysis

Modified intent-to-treat (mITT) analysis set: all patients who were randomized and received at least one dose of study treatment

NRI, non-responder imputation; PGA, Physician's Global Assessment; QD, once daily
## Safety summary

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n=52)</th>
<th>TAK-279 2 mg QD (n=50)</th>
<th>TAK-279 5 mg QD (n=52)</th>
<th>TAK-279 15 mg QD (n=53)</th>
<th>TAK-279 30 mg QD (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (1.9)</td>
<td>0</td>
</tr>
<tr>
<td>Adverse events</td>
<td>23 (44.2)</td>
<td>31 (62.0)</td>
<td>28 (53.8)</td>
<td>28 (52.8)</td>
<td>31 (59.6)</td>
</tr>
<tr>
<td>Adverse events leading to discontinuation&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1 (1.9)</td>
<td>1 (2.0)</td>
<td>1 (1.9)</td>
<td>1 (1.9)</td>
<td>2 (3.8)</td>
</tr>
<tr>
<td>Most frequent adverse events&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19</td>
<td>1 (1.9)</td>
<td>6 (12.0)</td>
<td>4 (7.7)</td>
<td>6 (11.3)</td>
<td>7 (13.5)</td>
</tr>
<tr>
<td>Acne</td>
<td>0</td>
<td>0</td>
<td>1 (1.9)</td>
<td>3 (5.7)</td>
<td>2 (3.8)</td>
</tr>
<tr>
<td>Acneiform dermatitis</td>
<td>0</td>
<td>0</td>
<td>1 (1.9)</td>
<td>1 (1.9)</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1 (1.9)</td>
<td>3 (6.0)</td>
<td>1 (1.9)</td>
<td>1 (1.9)</td>
<td>0</td>
</tr>
</tbody>
</table>

*Adverse events leading to drug discontinuation and early termination in 5 patients included:
- CPK increased (30 mg)
- pericardial effusion and pleural effusion (15 mg)
- tachycardia and syncope (5 mg)
- lymphocyte count decreased (2 mg)
- atrial fibrillation (placebo)
One additional patient (30 mg) permanently discontinued study drug due to an adverse event of hypertensive urgency, but remained on study.

*No patients discontinued owing to COVID-19

*AEs reported by ≥3 patients in any treatment group (events elicited by laboratory testing are not included)

Number of patients (percent)

CPK, creatine kinase; QD, once daily
## Common terminology criteria for adverse events Grade ≥3

<table>
<thead>
<tr>
<th>Treatment-emergent laboratory shifts</th>
<th>Placebo (n=52)</th>
<th>TAK-279 2 mg QD (n=50)</th>
<th>TAK-279 5 mg QD (n=52)</th>
<th>TAK-279 15 mg QD (n=53)</th>
<th>TAK-279 30 mg QD (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Anemia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Thrombocytopenia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CPK elevation</td>
<td>1 (2)</td>
<td>0</td>
<td>0</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>ALT elevation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AST elevation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Creatinine elevation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cholesterol elevation, Wk 12</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Triglyceride elevation, Wk 12</td>
<td>1 (2)</td>
<td>1 (2)</td>
<td>0</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Worsening of proteinuria</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*a* Post-hoc analysis, percent rounded up to nearest integer  
*b* Treatment-emergent and ≥1 grade increase from baseline  
ALT, alanine aminotransferase; AST, aspartate aminotransferase; CPK, creatine kinase; CTCAE, common terminology criteria for adverse events; QD, once daily; Wk, week
Conclusions

• **Primary endpoint (PASI 75 response at Week 12) achieved with TAK-279 doses ≥5 mg**
  – 68% of patients on 15 mg QD and 67% of patients on 30 mg QD achieved PASI 75

• **Secondary endpoints also achieved with TAK-279 at doses ≥5 mg**
  – Greater proportion of patients achieved PASI 100 or PGA 0 at the highest dose of TAK-279
  – At 30 mg QD dosing, 33% of patients achieved clear skin

• **Generally low rates of TEAEs: COVID-19, acne, acneiform dermatitis and diarrhea were the most common TEAEs**
  – One patient with two SAEs at Day 35, 10 days after last administration of 15 mg dose (not related)
  – Few patients with TEAEs leading to treatment discontinuation (1–2 per treatment group)

• **Overall, efficacy with safety findings from this phase 2b study support further larger studies of TAK-279 in psoriasis**

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PASI, Psoriasis Area and Severity Index; PGA, Physician’s Global Assessment; QD, once daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event
**Potential for Best-in-Class Oral Treatment Option for Psoriasis**

- High selectivity for TYK2 over JAKs (1,470,588-fold vs. JAK1)
- Potent TYK2 inhibition with well tolerated, once daily oral dosing
- Robust efficacy in Ph2b Psoriasis study, including 33% of patients on 30mg achieving clear skin at 12 weeks (PASI 100 / PGA 0)

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**Psoriatic Arthritis**  
*Phase 2b Readout*

- FY23

**Initiate Psoriasis**  
*Phase 3*

- FY23

**Initiate IBD, SLE**  
*Phase 2*

- FY23

**Initiate Other Indications**  
*Phase 2*

- FY24 and beyond

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**Potential for Psoriasis regulatory filing in FY25-27 timeframe**

1. Phase 3 study design of Psoriasis to be finalized with regulatory input
Today’s Topics

1. Efficacy and safety results from the randomized, double-blind, placebo-controlled phase 2b trial of TYK2 inhibitor NDI-034858* in moderate-to-severe psoriasis

Graham Heap, MBBS, PhD
Vice President Global Program Leader, R&D

2. Q&A Session

Panelists

Andy Plump
President, R&D

Uthra Sundaram
Executive Vice President & Head of Global Product & Launch Strategy, Global Portfolio Division

Graham Heap
Vice President Global Program Leader, R&D
APPENDIX
Additional Slides from the AAD Presentation
Primary endpoint: PASI 75 at Week 12

NRI analysis

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Proportion of patients achieving PASI 75</th>
<th>Difference (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (n=52)</td>
<td>5.8%</td>
<td>12.3 (0.04, 24.60)</td>
<td>0.052</td>
</tr>
<tr>
<td>TAK-279 2 mg QD (n=50)</td>
<td>18.0%</td>
<td>38.5 (23.52, 53.40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TAK-279 5 mg QD (n=52)</td>
<td>44.2%</td>
<td>61.9 (47.56, 76.20)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TAK-279 15 mg QD (n=53)</td>
<td>67.9%</td>
<td>61.5 (47.46, 75.61)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TAK-279 30 mg QD (n=52)</td>
<td>67.3%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p value from a Cochran-Mantel-Haenszel test, with prior biologic treatment included as a stratification factor, comparing the proportion of patients in the treatment group versus placebo

Modified intent-to-treat (mITT) analysis set: all patients who were randomized and received at least one dose of study treatment

CI, confidence interval; NRI, non-responder imputation; QD, once daily
Representative PASI 75 and PASI 90 responses with TAK-279 30 mg QD

PASI, Psoriasis Area and Severity Index; QD, once daily
Hematological parameters and CPK

- **Neutrophil count (ANC)**
  Reference range 1.8–8.0 (10^9/L)

- **Lymphocyte count (ALC)**
  Reference range 1.0–5.0 (10^9/L)

- **Creatine kinase (CPK)**
  Reference range 25–210 (U/L)

- **Hemoglobin**
  Reference range 136–180 (g/L)

- **Platelets**
  Reference range 140–400 (10^9/L)

Data are mean ± standard deviation

- Mean lab values and changes from baseline do not reveal adverse trends in cell counts
- CPK shows some variability at 15 mg and 30 mg with large error bars
### Hepatic and renal parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine aminotransferase (ALT)</td>
<td>10–53 U/L</td>
</tr>
<tr>
<td>Aspartate aminotransferase (AST)</td>
<td>14–43 U/L</td>
</tr>
<tr>
<td>Bilirubin (total)</td>
<td>0.25–1.21 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.82–1.44 mg/dL</td>
</tr>
<tr>
<td>Estimated glomerular filtration rate (eGFR)</td>
<td>&gt;90 mL/min/1.73 m²</td>
</tr>
</tbody>
</table>

Data are mean ± standard deviation

- Mean lab values and changes from baseline do not reveal adverse trends for liver enzymes, creatinine or eGFR
Lipid parameters

- Mean lab values and changes from baseline do not reveal adverse trends in cholesterol, HDL, or LDL
- Triglyceride elevation is minimal

**Cholesterol (total)**
Reference range 100–200 mg/dL

**Triglycerides**
Reference range 50–150 mg/dL

**HDL cholesterol**
Reference range 0.91–1.55 mmol/L

**LDL cholesterol**
Reference range 50–130 mg/dL

**LDL/HDL ratio**
Reference range 0.5–3.0

Data are mean ± standard deviation
HDL, high-density lipoprotein; LDL, low-density lipoprotein