### Section 1

**External request:** Submission from Puma Biotechnology, Inc.

Request inclusion of neratinib in the treatment algorithm (as opposed to the footnote) as extended adjuvant treatment following treatment with adjuvant trastuzumab-based therapy per FDA indication in the following:

- Systemic Adjuvant Treatment – Hormone Receptor-Positive (HR+) – HER2-Positive Disease (BINV-5)
- Preoperative Systemic Therapy: Adjuvant Therapy (BINV-13)
- Preoperative Systemic Therapy for Inoperable or Locally Advanced Breast Cancer (Non-Inflammatory) (BINV-15).
- Preferred and Other Adjuvant Regimens to follow trastuzumab-based regimens (BINV-K; Page 1 and pages 4,5).

Based on a review of data and discussion, the panel consensus was to not make changes to the current recommendations. See Submission for references.

### Bracket Table

<table>
<thead>
<tr>
<th>Institution Vote</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

### Section 2

**External request:** Submission from Novartis Pharmaceuticals Corporation.

Request for the Panel to consider ribociclib in combination with NSAI/tamoxifen with ovarian suppression or ablation as the preferred first-line treatment option for premenopausal HR+/HER2- advanced breast cancer in those with no prior endocrine therapy within 1 year.

Based on a review of data and discussion, the panel consensus supported the inclusion of ribociclib in combination with tamoxifen as a preferred option for first-line therapy with ovarian suppression or ablation for premenopausal patients with HR+, HER2- metastatic breast cancer. This is a category 1 recommendation. See Submission for References.

### Section 3

**Internal request to remove the following chemotherapy regimens for recurrent or stage IV (M1) disease:**

- CAF/FAC (cyclophosphamide/doxorubicin/fluorouracil)
- FEC (fluorouracil/epirubicin/cyclophosphamide)

The panel consensus supported the removal of the noted combination regimens as treatment options for patients with recurrent or stage IV (M1) disease.

### Institution Vote

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>ABSTAIN</th>
<th>ABSENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>0</td>
<td>0</td>
<td>16</td>
</tr>
</tbody>
</table>

**Process document updated 3.9.18**