### Guideline Page and Request

**BINV-21 and BINV-O**

Internal request from institutional review. Request the addition of first-line ribociclib plus fulvestrant to the list of options for postmenopausal women with HR-positive, HER2-negative recurrent or stage IV (M1) disease based on the MONALEESA-3 data presented at ASCO.

External submission from Novartis Pharmaceuticals Corp. Request inclusion of ribociclib in combination with fulvestrant as treatment in the first- and second-line setting of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer.

External submission from AstraZeneca. Request the addition of fulvestrant plus ribociclib as a combination therapy option for the treatment of HR-positive, HER2-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.

### Panel Discussion/References

Based upon review of the data in the noted references and Panel discussion, the consensus was to include ribociclib in combination with fulvestrant as a preferred regimen option for postmenopausal women with HR-positive, HER2-negative recurrent or stage IV (M1) disease. This is a category 1 recommendation. Since all CDK 4/6 inhibitors have similar efficacy profiles in combination with AI, the panel has included CDK 4/6 + fulvestrant as a first-line option under preferred regimens for “for women who are postmenopausal or premenopausal (receiving ovarian suppression or ablation with an LHRH agonist) with HR-positive, HER2-negative metastatic breast cancer” noting that “only one trial has combined fulvestrant with a CDK4/6 inhibitor (ribociclib) in the first-line setting”

See Submissions for References.

### Institution Vote

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