Expanded Access or Compassionate Use for the [Investigational New Drug Product] BR55, a targeted ultrasound contrast agent proposed for the detection of active inflammation in the gastrointestinal tract of patients with Crohn's disease

At this time, Bracco Diagnostics Inc. [Bracco] does not offer access to our unapproved Investigational New Drug Product, BR55 via expanded access or compassionate use and believes that participating any ongoing or future clinical trials is the best way to access this medicine that is not yet approved by U.S. Food and Drug Administration.

Bracco has considered many factors in this decision, including our ability to maintain supply for the enrollment of patients in current on-going and planned clinical trials, and the importance of enrollment into those clinical trials to make reasonable assessments of any potential risk versus benefit for patients which can best be done in the clinical trial setting.

Should Bracco decide to consider expanded access to BR55 in the future, this guideline will be updated, and we will evaluate and respond to each expanded access request on a case-by-case basis using criteria that ensures such requests are considered in a fair and consistent manner.

If you or a family member are/is interested in gaining access to our investigational therapy, we encourage you to consult with your physician regarding the possibility of participating in our clinical trials. For additional information about this posted guideline or if you are a treating physician requesting expanded access, please contact us via the link on this website: https://www.bracco.com/en-us/get-touch. We anticipate acknowledging receipt of such inquiries within three business days.

The posting of this guideline by Bracco shall not serve as a guarantee of access to any specific investigational drug by any individual patient. In accordance with the 21st Century Cures Act, Bracco may revise this expanded access guideline at any time. The guideline will be updated with a hyperlink or other reference to the expanded access record on clinicaltrials.gov after such record becomes active.

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