Clinical Trials and EUA Update

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Agenda

- Original EUA trials/data
- Recent clinical trial updates
- EUA updates

Current Emergency Use Authorizations (EUAs)

Drug	Bamlanivimab (Lilly)	Casirivimab/Indevimab (Regeneron)
Trial	BLAZE-1[1] (Ph2 interim results) Arms (1:1:1:1) N=452 • Bam 700 mg, Bam 2800 mg, Bam 7000 mg, placebo	2067[2] (Phase 1-3 interim results) Arms (1:1:1) N=799 • REGEN-COV 2.4g, REGEN-COV 8g, placebo
Primary Endpoint	**D11 change in log viral load** 2800mg arm: −0.53 versus placebo (p=0.02)	**D7 change in log viral load** Pooled treatment group=-0.36 (p<0.0001)
Secondary Endpoint	**Hospitalizations/ER visits** High risk patients (pooled)= ~70% decrease 4% (4/95) vs. 15% (7/48) placebo	**Medically attended visits** High risk patients (pooled)= ~70% decrease 3% (4/151) vs. 9% (7/78) placebo
Status	EUA (November 9, 2020): Bam 700 mg high risk outpatients based on potential to decrease hospitalizations	EUA (November 21, 2020): REGEN-COV 2.4g high risk outpatients based on potential to decrease hospitalizations

1. https://www.nejm.org/doi/full/10.1056/NEJMoa2029849
2. https://www.fda.gov/media/144468/download, https://www.nejm.org/doi/full/10.1056/NEJMoa2035002?query=recirc_curatedRelated_article

Recent Data: Bamlanivimab and Etesevimab

Drug	Bamlanivimab / Etesevimab	Bamlanivimab	Bamlanivimab / Etesevimab
Trial	BLAZE-1[1] (Ph2 final results) Arms: (1:1:1:1), (1:1) N=577 • Bam 700 mg, 2800 mg, 7000 mg, placebo • Bam 2800mg/ ete 2800mg, placebo	BLAZE-2[2] (post-exposure prophylaxis in LTCF) Arms: (1:1) N=299 • Bam 4200mg, placebo	BLAZE-1[3] (Ph3) Arms: (1:1) N=1035 • Bam 2800mg/ete 2800mg, placebo
Primary Endpoint	**D11 change in viral load** Combo arm: −0.57; p=0.01	**Prevention of symptomatic COVID-19** OR=0.2; p=0.00026 80% reduction for residents	**Hospitalizations/death D29** 70% reduction vs. placebo 2.1% (11/517) vs. 7% (36/518); p= 0.0004 Death: 10/518 placebo, 0/517 bam/ete
Secondary Endpoint	**Hospitalizations/ER visits** High risk patients ~70% decrease Pooled mono= 4% (4/101), Combo= 0% (0/31) placebo= 13.5% (7/52)		Viral load and symptom decrease all significant
Status	EUA under review	EUA to be submitted	Press release

1. https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-prevented
2. https://investor.lilly.com/news-releases/news-release-details/new-data-show-treatment-lillys-neutralizing-antibodies
3. https://jamanetwork.com/journals/jama/fullarticle/2775647

Recent Data: Casirivimab and Imdevimab

Drug	Casirivimab / Imdevimab
Trial	Phase 3 prevention[1] (interim) Arms: (1:1) N=400 • REGEN-COV 2.4g SQ • placebo
Primary Endpoint	**Symptomatic infection** 8/223 placebo vs. 0/186 REGEN-COV **Symptomatic and asymptomatic** 23/223 placebo vs. 10/186 REGEN-COV.
Status	Press release

1. https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-positive-interim-data-regen-covtm-antibody

EUA Updates Bamlanivimab[1]

- **Shortened infusion times** (Section 2.4)

Drug: Add 20 mL of bamlanivimab (1 vial) to a prefilled infusion bag and administer as instructed below		
Size of prefilled 0.9% Sodium Chloride infusion bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	270 mL/hr	16 minutes
100 mL	270 mL/hr	27 minutes
150 mL	270 mL/hr	38 minutes
250 mL	270 mL/hr	60 minutes

- **Addition of new symptoms to Hypersensitivity and infusion-related reaction Warning and Precaution** (Section 5.1)

- **Addition of Warning and Precaution for clinical worsening after bamlanivimab administration** (Section 5.2)

1. https://www.fda.gov/media/143603/download

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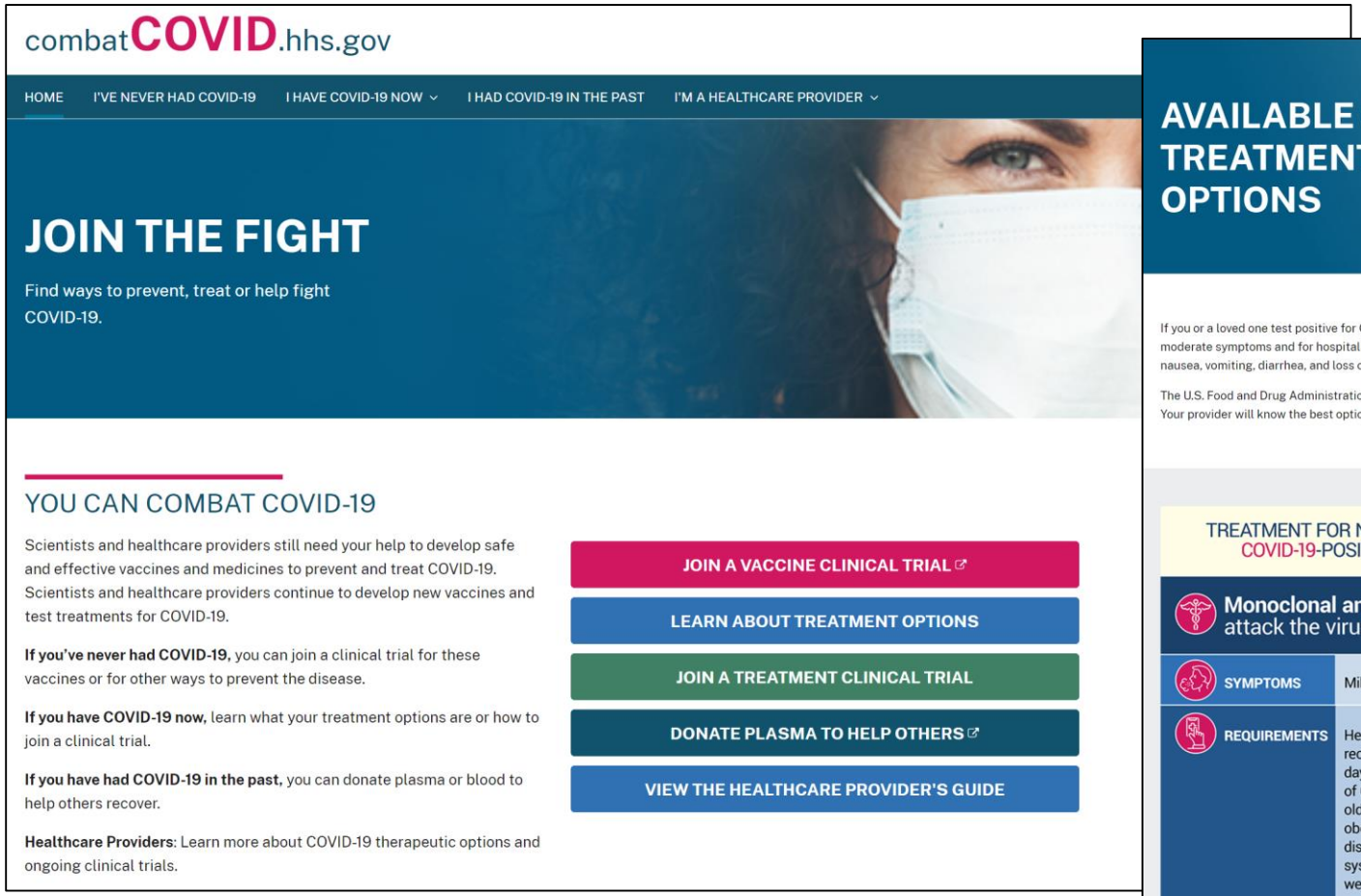

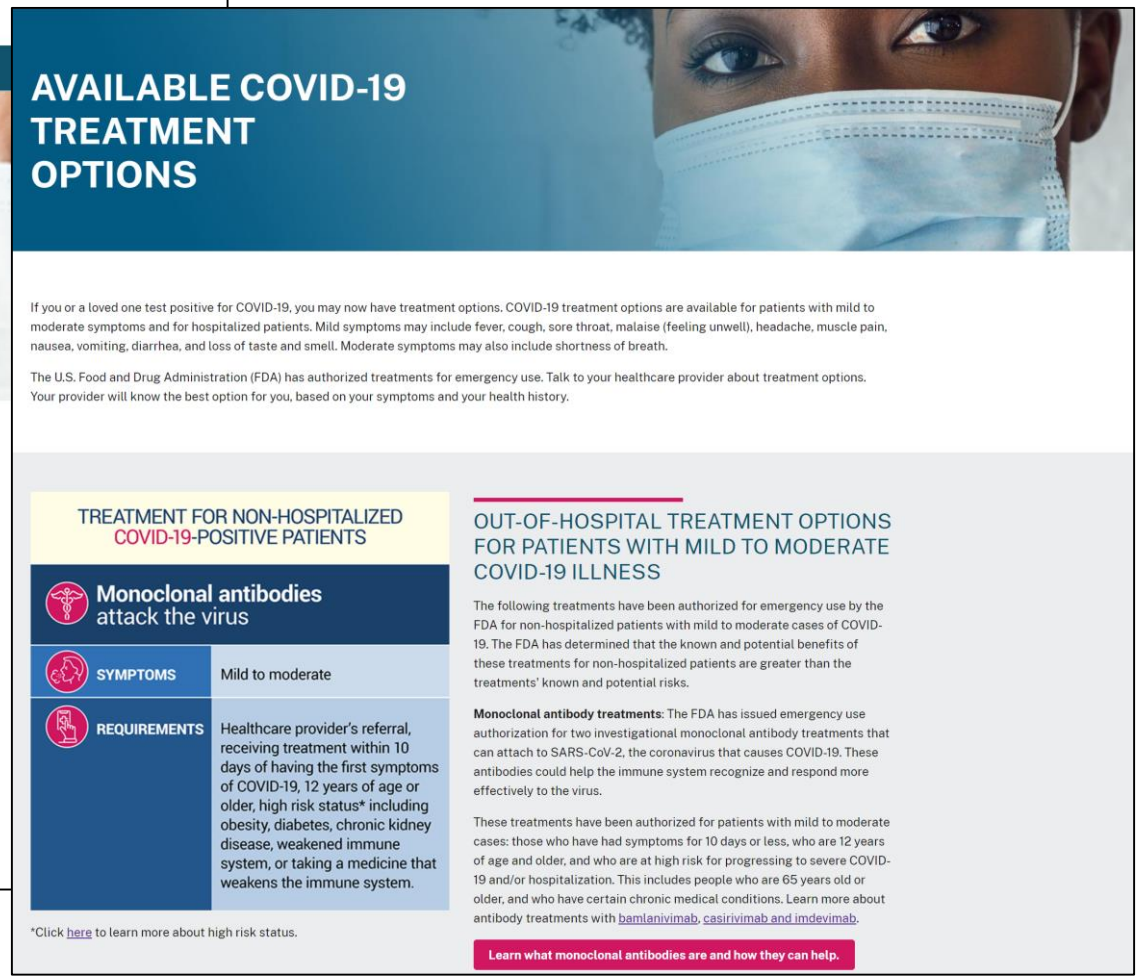

http://combatCOVID.hhs.gov


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