How to highlight study cautions

Setting	Suggested language
Preliminary research (e.g., unpublished scientific meeting presentations)	"The findings presented are preliminary. Because the findings have not undergone final peer review, they have yet to be independently verified, and may change."
Inherently weak designs	
Animal or lab study	"Do not assume that the results of animal studies apply to humans: it generally takes years to know if they translate to people."
Cross sectional studies	"Because all information was collected simultaneously, you cannot know if the exposure caused the outcome, or visa versa."
Ecologic studies (e.g., International comparison of dietary fat consumption vs. colon cancer mortality rate)	"The study compared the average level of [exposure] in [different groups] and [outcome] in these [groups] - there is no way to know if the people [with exposure] actually had [had outcome]."
Models (e.g., decision analysis)	"The findings are based on hypothetical relationships which may not exist."
No control group	"Because there was no control group (i.e., a group not [taking drug]), it is impossible to know if [drug] accounts for the findings."
Small study (e.g., less than 30 people)	"These findings are based on a small study; larger studies are needed to really understand how much the intervention works."
Surrogate outcomes	"We cannot know whether [surrogate outcome - for example, cholesterol lowering] will translate into a clinically meaningful outcome such as [patient outcome - for example, heart attack death]."
Classic designs	
Randomized trial	
Extrapolation	"The findings may not apply to people who differ from those in the study (e.g., people with less severe disease or at lower risk for bad outcomes)"
New interventions	"The findings are based on short-term data. Short-term benefits may diminish and side effects may emerge over time. Longer term studies are needed."
New drugs	"[Drug] is a new drug (approved in [20xx]). As with all new drugs, we don't know how its safety record will hold up over time. In general, if there are unforeseen, serious side effects, they emerge after the drug is on the market when a large enough number of people have used the drug." If this is the first drug in its class, consider adding: "since this is the first drug of its kind to receive FDA approval, experience is particularly limited."
Observational studies (with a control group)	
Trial <u>not</u> possible (e.g., harmful exposure)	"Because the study was not true experiment, there may be something else about the people who happened to be exposed to [exposure] that explains the findings."
Trial possible (e.g., beneficial exposure)	"Because the study was not a true experiment, it is not known if changing [the exposure] will alter the outcome. There may be something else about the people who happened to be exposed to [exposure] that explains the findings. A randomized trial is needed before widespread adoption of [intervention]."
All studies	"The benefit of [any action/intervention] should be weighed against the [side effects, inconveniences, costs, etc.]."

Bottom Line **Use cautions – all studies have them.**
Consider not reporting preliminary or inherently weak research.